

SPLIT-NUT PRECISION FASTENERS

INVENTOR

Yosef Freedland

CROSS-REFERENCE TO EARLIER FILED APPLICATIONS

5 The present application claims the priority of earlier filed International patent application serial no. PCT/IB00/00364 filed March 28, 2000; U.S. provisional application for patent serial no. 60/193,000 filed March 28, 2000; U.S. provisional application for patent serial no. 60/174,386 filed January 3, 2000; U.S. patent application serial no. [to be added] filed December 18, 2000, which is a divisional application of U.S. Patent Application Serial No. 08/601,177, filed February 14, 1996, now U.S. Patent No. 6,162,234, issued December 19, 2000, which is a continuation-in-part application of co-pending U.S. Patent application serial number 08/184,121, filed on January 21, 1994, which is a continuation-in-part application of U.S. Patent application serial number 08/034,269
10 filed March 23, 1993, the entire disclosures of which are hereby incorporated by reference.

FIELD OF THE INVENTION

The present invention relates to orthopedic devices for fastening biological tissues under a controlled degree of tension and in particular to systems comprising a split-nut, winged bolt and/or transverse compaction screw.

BACKGROUND OF THE INVENTION

15 Orthopedics is often rightfully called "bone carpentry", as its object is to screw, staple or bolt pieces of bone together as closely and as precisely as possible so that the bone can heal together. Fasteners that hold the bones together are known. In surgery, repair must take place within the time space of the few hours of the surgery. The human tissue cannot simply be cut and moved out of the
20 way in order to facilitate the repair of the bones, as the resultant healed muscles and ligaments that

were cut will not function properly after healing. Further, orthopedic devices must remain in the body at least until the tissue heals and usually much longer.

The anterior cruciate ligament (ACL) spans the knee joint and attaches to the upper bone, the femur and the lower bone, the tibia, to maintain smooth movement between their adjacent bone surfaces during knee movement. It rips in sporting accidents, requiring replacement with a graft that is fastened at one end to the femur, and at its opposite end to the Tibia. The ligament graft is typically secured with screws to these two bones. Such fasteners cannot easily adjust the tension on the ligament graft once installed. Hence, if, during surgery, the replacement ligament is perceived to be loose, allowing excessive play between the femur, and the tibia, it is often left this way, leading to discomfort and arthritis in the knee postoperatively.

In surgical repair of a fractured mid-thigh bone, an intramedullary rod is inserted through the long canal that runs the length of the thighbone and one end is attached to the bone near the hip joint while the other end is secured to bone near the knee joint. Winged intramedullary rods are known. The Brooker-Will™ rod, for instance, has two thin fins that slid out of a long hollow rod and anchor in the soft bone near the knee. The fins tend to migrate in the soft bone so the bones misalign and the fins often fail to retract through thin slots in the long hollow rod, preventing removal of the rod at a later date.

U.S. Patent 436,101 to Freedland discloses a multi-winged anchor for fractures of the femoral neck. U.S. Patent 4,721,103 to Freedland discloses an intramedullary rod, which has two wings that expand outwardly. U.S. Patent 4,862,883 to Freedland discloses an intramedullary rod placed within the central longitudinal cavity in the femur. U.S. Patent 5,098,433 to Freedland discloses a toggle, bolt with wings that collapse so that the wings along with the body of the toggle bolt can be removed from the bore in the bone. These Winged Intramedullary rods have multiple moving parts that, and if they are left in the body for a long period, they tend to corrode, leading to problems in retracting the wings and removing the rod.

A threaded shaft with a threaded nut for fastening body tissue is known. Fasteners that slide and rotate on a rigid shaft are known. U.S. Patent 5,098,433 to Freedland discloses a slide-on nut arrangement where the nut is secured by a cross pin to the shaft and an outer ring on the nut rotates to vary the force on the adjacent tissues.

Closing tissue during surgery with suture knots during surgery is slow and cumbersome. Many different devices, which attempt to facilitate the tying of knots, have been disclosed. To date, however, very few surgical devices, which can be used in place of a knot in a suture, have been developed. Banded clamps made of rigid material that join two ends of a suture are known. The Y-Knot by Innovasive, Inc. fastens two ends of a suture loop simultaneously. The Y-Knot™ includes a compression ring, or band, and a single disk having a single annular groove and a single centrally located bore. A suture is retained between the band and the annular groove of the disk.

Banded fasteners, wherein a soft cylindrical jacket is compressed against a cable by a band that surrounds it, are known. U.S. Patent 5,626,590 discloses a cylindrical jacket made of a deformable material around which a rigid band is placed. US Patent 590,294 discloses a device having a long cylindrical jacket with an internally and externally threaded, split-nut and collet. All of these banded fasteners utilize long cylindrical jackets wherein only a portion of the jacket exerts pressure on the cable or shaft via the pressure of the band that surrounds it making them inefficient fasteners in size and in strength.

Screws that traverse a bore in a bone such as the Bone Mulch™ screw by Arthrotec Endoscopy are utilized for anchoring or fastening large ligaments to a knee bone. This fastener does not cause the graft to become compacted against the adjacent bone.

The above-mentioned references disclose a variety of orthopedic devices, which attempt to meet the needs in the field. However, many needs in the field of orthopedic surgery go unmet. The present invention provides a variety of tensioning devices capable of being implanted

SUMMARY OF THE INVENTION

The present invention overcomes the disadvantages of known related orthopedic fasteners and thus is generally directed to orthopedic devices that can be used to control the amount of tension and compression or distance between biological tissues.

The present invention includes a toggle bolt with a single cross piece that rotates into position, rather than tradition toggle-like wings. Since it is a single wing, the size of this wing, and the shaft, can be maximized. This invention contemplates a metal shaft for the fastener so that it can withstand the tremendous stress along the longitudinal axis. At the opposite end, while this cross piece can be rotated back to the pre-insertion position by using a tool, it is designed to take advantage

of the dissolvability of many materials on the orthopedic market today. In such case, the single toggle is made from a dissolvable material so that the problems of removal can be circumvented.

The present invention, in the Suture Nut design, has a relatively non-deforming cylindrical jacket that is cut in sections for their entire length and surrounded by a relatively rigid band. This allows the Suture Lock to be compact and the sections of the split-nut to apply great pressure to the suture.

The dissolving material of the invention would ideally have great strength for a period of two or three menthes while the bone heals and then would rapidly dissolve so that the rod could be removed from the bone when the surgeon wishes. In a preferred embodiment, the cross piece can be made of a very durable dissolving plastic, one that is known to last in the body an inordinate amount of time, but that has tremendous strength. Once the healing takes place, a catalyst can be introduced into its proximity to facilitate its dissolution. The present invention contemplates a means of introducing such a catalyst even though the crosspiece is embedded deep in the knees and the entry to the thighbone is located far away at the hip.

The technique for reconstructing a fractured hip would be to make a bore in the bone from the top of the thigh bone, down into the knees, insert the fastener with its cross piece initially parallel to the shaft. The crosspiece would be rotated perpendicular to the shaft once it is past the mid-thigh fracture and in the knee. The surgeon would then pull up on the shaft so that the crosspiece would impact on the bone around it and bring the lower bone fragment into the upper bone fragment, impacting them together.

At the other end, a nut would be placed on the threaded shaft and rotated until it pressed against the upper edge of the hip bone and the excess shaft would be cut off. In such a procedure, the amount of excess shaft that would protrude out of the bore in the hip, would be dependent up the placement of the cross piece, the length of the thigh bone, and the amount of impaction that is achieved between the bone fragments.

Having a one-size-fits-all is preferable from an economic standpoint to requiring the hospital to carry many different lengths of the same rod. Yet, to allow for the many different lengths of hips that must be fastened, means that a typical compression rod must be, perhaps, ten centimeters longer than its final state after being cut to size. This necessitates turning the nut many revolutions before it comes to rest against the bone and apply proper compression. The split-nut is designed to speed this

process for the surgeon so that rather than rotating the nut all the way down the shaft, it can slide along the shaft until into position and then rotate in order to apply precision compression to the bone pieces. The present invention relates to fastening and applying tension to materials in vivo with a threaded nut on a threaded rod in a rapid fashion. The speed nut is a split-nut whose sections expand
5 to allow it to slide until encompassed by a compression ring at the surface of a bone. It is rotated while compressed against the bone surface, it causes a threaded rod to move in or out of a bore in the bone, and thereby apply compression to the bone pieces.

In another embodiment of the split-nut, a portion of the shaft is replaced by a soft tissue link, such as an eye, so that the soft tissue becomes incorporated as the structures heal. In this case, the
10 split-nut is rotated to pull the rod out of the bore in the bone, increasing tension on a ligament or muscle that is attached to the eye at the opposite end of the shaft.

This embodiment is particularly useful in fastening a large ligament such as the ligaments of the knee, with precise tension. The speed nut is a threaded nut fastener that compresses against the hard surface of the Tibia, rather than fastening within the softer internal bone as do screws and
15 staples, and over a large surface area, giving it much greater fixation strength. It rotates against the bone surface against which it is compressed to bring a threaded rod attached to a graft, out of the bore, thereby putting adjustable tension on the graft. To save time in rotating the fastener up to the surface of the tibia, it is split so that its sections temporarily distend and it slides rather than rotates to reach the surface of the Tibia. Once at the bone surface, its pieces slide against each other so their
20 bore size decreases and the fastener threads mesh with the threaded rod. With the speed nut compressed against the bone surface, it causes the rod to moves through rotation only. The tension of the graft can be measured and readjusted with joint motion in between measurements to help settle the graft in place, without affecting the strength of the fastener, a technique presently not available in state-of-the-art fasteners.

25 In summary, the speed nut, is stronger than typical knee ligament fasteners, and adjusts the ligament tension where adjustment typically cannot be made. It is designed to install rapidly without time wasted on rotating the nut up to the bone surface.

The present invention includes a donut-shaped fastener, cut and banded in pie-like sections which easily and quickly reaches a desired position on a shaft or cable. At the opposite end is a

tissue receptacle that when working in conjunction with the SPLIT-NUT, precisely adjusts tissue position.

The various embodiments of the pivot wing in the PRECISION COMPRESSION RODS can be made of dissolvable materials. A novel method is shown in the patent whereby such dissolvable materials, even when buried deep in the bone, can be made to dissolve more rapidly when in contact with a catalytic agent.

In one aspect the present invention provides a ball-and-socket nut assembly. The nut generally has a convex-shaped surface and mates with a flanged concave-shaped socket. The flanged socket has a slit to allow passage of the convex-shaped nut on a threaded rod as it is seated in the socket. The convex-shaped nut swivels in the socket, allowing the threaded rod to conform to a variety of bore angles. The flanged socket in which the nut rests compresses against the hard surface of the Tibia, rather than fastening within the softer internal bone as do screws and staples, and covers a large surface area, giving it much greater fixation strength than state-of-the-art bone screws. When the nut assembly is implanted into a bone, the flange is disposed on the surface of the bone and the socket is disposed within a bore in the bone. The nut is rotated while seated in the socket, and the flange compresses against the bone surface and causes the threaded rod to move in or out of a bore in the bone, and thereby adjusts the distance or forces between reconstructed body tissues.

In one embodiment of the threaded shaft or bolt, a portion of the shaft is replaced by a retainer, such as an eye, for soft tissue. A soft tissue graft is attached to the eye and the split-nut is rotated to pull the rod out of the bore in the bone, thereby increasing tension on the soft tissue graft that is attached to the eye at the opposite end of the shaft. The tension of the graft can be measured and readjusted with joint motion in between measurements to help settle the graft in place, without affecting the strength of the fastener, a technique presently not available in state-of-the-art fasteners. This embodiment is particularly useful in fastening large ligaments such as the ligaments of the knee, with precise tension while the ligament graft fibers incorporate into the surrounding bone, providing a knee that functions properly.

In another aspect, the present invention provides a split-nut, or speed-nut, fastener that can be used in conjunction with many known implantable orthopedic fasteners. The snap ring nut is a split-nut whose sections expand to allow it to slide until encompassed by a compression ring. It is rotated while compressed against the bone surface and causes a threaded rod to move in or out of a bore in

the bone, and thereby change the distance between the body tissues. The split-nut is designed to speed the threading process for the surgeon by circumventing the need to thread the nut down the entire length of the screw. Instead, the split-nut is slid approximately all the way down the shaft until it is in proper position, the split-nut sections are compressed toward each other and grasp the threaded shaft so that it will rotate on the threaded shaft so as to change the distance between biological tissues. The split-nut is particularly useful when used in combination with long, or one-size-fits-all, threaded shafts or screws. The one-size-fits all screw is preferable from an economic standpoint since it minimizes the need for a hospital to carry many different lengths of the same rod or screw. In one embodiment, the speed nut is used in place of the solid nut of the ball-and-socket fastener noted above.

In another aspect, the present invention provides a pivot wing bolt with a single crosspiece that rotates into position. Since it is a single wing, the size of the wing, and the shaft, can be maximized. In a specific embodiment, the invention provides a metal shaft for the fastener so that it can withstand the tremendous stress along the longitudinal axis. At an opposite end, the crosspiece can be rotated to a deployed position and back to the pre-insertion position by using a tool. In another preferred embodiment, the crosspiece is made of a material that dissolves or degrades in a physiological environment. The dissolving material will preferably maintain its integrity for a period of about two or three months during which time the bone in which it is implanted heals. Near the end of such a period, the material will generally dissolve or degrade so that the rod could be removed from the bone as desired. In a specific embodiment, the crosspiece can be made of a very durable dissolvable plastic, one that is known to last in the body an extended period of time and that has sufficient strength to provide acceptable performance. Once the bone in which the toggle bolt has been implanted has healed, a catalyst, such as an enzyme, can be introduced into its proximity to facilitate its dissolution. Accordingly, the present invention also provides a means of introducing such a catalyst into the bone in proximity of the crosspiece even though the crosspiece is embedded deep in the knees and the entry to the thighbone is located far away at the hip.

In another aspect, the present invention provides a suture nut. The suture nut generally comprises a relatively non-deforming cylindrical jacket that is cut into two or more sections throughout its entire length and is surrounded by a relatively rigid band. The suture nut is compact,

and the sections of the suture nut apply a significant amount of pressure to a suture engaged with the suture nut.

Another aspect of the invention provides a transverse impaction screw that is implantable in bone and is used to increase the forces between biological tissues such as a ligament, tendon, fascia or muscle and a bone. The transverse impaction screw is threaded into a bone preferably approximately normal to a bore through the bone. The transverse impaction screw has a smooth, flat, narrow central region. It is installed perpendicular to the linear axis of a bore in a bone, such as the femur, and initially, the flat section spans the bore such that the short axis defining the width of the flat section is placed parallel to the axis of the bore. The biological tissue is draped over. The flat section of the screw and the screw is turned such that the short axis that defines the width of the flat section is perpendicular to the axis of the bore thereby occupying a large portion of the transverse diameter of the bore. By so doing, the screw pushes the ligament graft radially outward and brings it into contact with the surrounding bone matrix. The ligament is thus compressed into the matrix thereby increasing the bond and resultant strength of attachment between the two.

Another aspect of the invention provides a flanged ball-and-socket assembly comprising: a nut having a convex hemispherical surface having an internal threaded bore for receiving a threaded shaft;

an approximately hemispherical concave socket adapted to receive, mate with and retain the nut, the socket having a hole and slot through a portion thereof for receiving a portion of a threaded shaft engaged with the nut, wherein the slot and hole is smaller in size than the nut; and a flange attached to a portion of the periphery of the socket, the flange having a notch through a portion thereof, wherein the notch is sufficiently large in size to permit passage of the nut into the socket.

Specific embodiments of the flanged ball-and-socket assembly include those wherein: 1) the nut further comprises tool engaging means adapted to receive a tool that can be used to drive or rotate the nut when engaged with a threaded shaft; 2) the tool engaging means comprises a recess; and/or 3) the nut assembly comprises a material suitable for use in orthopedic surgery.

Still another aspect of the invention provides a split-nut assembly comprising: two or more nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, and a second annular groove having a second diameter,

wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut; and

a band disposed in either of the first and second grooves to keep the two or more nut sections in assembly;

- 5 wherein the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove.

Specific embodiments of the split-nut assembly include those wherein: 1) the first groove is disposed adjacent a first end of the nut; 2) the second groove is disposed between the first groove and a second end of the nut; 3) the band is an o-ring or a snap ring; 4) a portion of the surface of the band mates with corresponding portions of the peripheral surface of the nut; 5) the nut further comprises a shoulder interposed the first and second grooves; 6) each groove further comprises a flange to keep the retainer in its respective groove; and/or 7) the split-nut comprises two nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, a second annular groove having a second diameter, a shoulder interposed the first and second grooves, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut; a snap ring disposed in either of the first and second grooves to keep the two or more nut sections in assembly; wherein, the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove; and a portion of the surface of the snap ring mates with corresponding portions of the peripheral surface of the nut.

Yet another aspect of the invention provides a pivot wing bolt tissue-tensioning assembly comprising:

a threaded shaft having a head comprising a swing stop and a wing mount; and

- 25 a single wing having an aperture engaged with the wing mount such that the wing is rotatably mounted on the wing mount;

wherein:

the linear axis of the wing is alignable with the linear axis of the threaded shaft; and

the swing stop limits the rotation of the wing about the wing mount to less than one revolution.

Specific embodiments of the pivot wing bolt tissue-tensioning assembly include those wherein: 1) the aperture in the wing is recessed; 2) the swing stop limits the rotation of the wing about the mount to about 90 degrees of revolution or less as measured from the linear axis of the shaft; 3) the threaded shaft has a longitudinal bore there through; 4) the longitudinal bore has two or more openings; 5) at least one of the openings of the longitudinal bore are disposed at or adjacent the head of the threaded shaft; 6) the wing mount comprises a hub and an axle; 7) the wing is flat and its width approximates or is less than the width of the head of the threaded shaft; 8) the pivot wing bolt tissue-tensioning assembly further comprises an installation tool that controls deployment of the wing from a first position parallel to the linear axis of the threaded shaft to a second position not parallel to the linear axis of the threaded shaft; 9) the installation tool has a first end that mates with at least one end of the wing; 10) the threaded shaft passes through the installation tool; 11) the installation tool is a sleeve having a first end that mates with at least one end of the wing; 12) the installation tool is rotated about and pushed along the linear axis of the threaded shaft to deploy the wing from a first position to a second position; 13) the pivot wing bolt tissue-tensioning assembly further comprises a nut assembly engaged with the threaded shaft; 14) the nut assembly is selected from the group consisting of a conventional nut, a split-nut assembly, and a ball-and-socket nut assembly; 15) the split-nut assembly comprises two or more nut sections which form a nut when assembled, the nut having a threaded bore, a first annular groove having a first diameter, and a second annular groove having a second diameter, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut; and a band disposed in either of the first and second grooves to keep the two or more nut sections in assembly; wherein the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove; and optionally wherein the sections of the split-nut are detached from one another or attached to each other by way of a living hinge; 16) the ball-and-socket nut assembly engaged with the threaded shaft comprises an approximately hemispherical convex nut having an internal threaded bore for receiving a threaded shaft; an approximately hemispherical concave socket adapted to receive, mate with and retain the nut, the socket having a slot and hole through a portion thereof for receiving a portion of a threaded shaft engaged with the nut, wherein the slot and hole is smaller in size than the nut; and a flange attached to a portion of the periphery of the socket, the flange having a notch through a portion

thereof, wherein the notch is sufficiently large in size to permit passage of the nut into the socket; 17) at least the wing comprises a material that deteriorates in an environment of use; 18) the wing comprises one or more dissolvable or biodegradable polymers; 19) the threaded shaft and the nut assembly are comprised of a material that deteriorates or degrades in an environment of use; 20) the threaded shaft, and optionally the nut, comprise buttress threads; 21) the buttress threads have a long slope on one surface and a short slope on another surface such that the nut sections expand in and out as the nut is moved linearly forward on the threaded shaft; 22) the pivot wing bolt tissue-tensioning bolt is used in conjunction with another tensioning assembly comprising a second threaded shaft having a second tissue retainer at a second end; and a second flanged ball-and-socket nut assembly; 23) the tissue-tensioning bolt assembly further comprises a tissue graft attached to each of the first and second tissue retainers; and/or 24) the tissue retainer is an eyelet or hole.

According to another aspect, the invention provides a transverse impaction screw comprising: a tool engagement means;

a threaded portion adjacent the tool engagement means; and

a non-threaded extended member attached to the threaded portion and comprising a flat surface.

Specific embodiments of the transverse impaction screw include those wherein: 1) the plane defining the flat surface is not parallel to the linear axis of the screw.

Yet other aspects of the invention provide a suture nut comprising:

two or more nut sections which form a nut when assembled, the nut comprising a non-threaded bore with a friction surface, a first annular groove having a first diameter, and a second annular groove having a second diameter, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut; and

a band disposed in either of the first and second grooves to keep the two or more nut sections in assembly;

wherein the nut sections are spaced from one another a first distance when the band is in the first groove and in closer proximity or in contact with one another when the band is in the second groove; and

the suture nut is capable of securing a suture when the band is disposed in the second groove.

Specific embodiments of the suture-nut include those wherein: 1) the suture nut further comprises a second non-threaded bore having a friction surface such that the suture nut can retain at least two suture portions; and/or 2) the bore is non-circular and the suture nut will retain at least two suture portions in the same bore.

5 The suture nut is used in a method of suturing an incision comprising the step of clamping one or more portions of a suture with a suture nut according to any one of the one described herein.

The tissue-tensioning bolt assembly can be used in a method of tensioning a biological tissue comprising the step of retaining and tensioning a biological tissue with a tissue-tensioning bolt assembly according to any of the ones described herein.

10 Another flanged ball-and-socket nut assembly comprises:

a longitudinally split-nut having a convex hemispherical surface having an internal threaded bore for receiving a threaded shaft;

an approximately hemispherical elongated concave socket adapted to receive, mate with and retain the nut, the socket having a hole and slot through a portion thereof for receiving a portion of a threaded shaft engaged with the nut, wherein the slot and hole is smaller in size than the nut, and wherein the socket has a first larger inner diameter section and a second smaller diameter inner section; and

a flange attached to the first larger diameter portion at the periphery of the socket, the flange having a notch through a portion thereof, wherein the notch is sufficiently large in size to permit passage of the nut into the socket; wherein

the socket is adapted to compress the split-nut when the split-nut is engaged with the second smaller diameter inner section of the socket.

Specific embodiments of the flanged ball-and-socket assembly include those wherein: 1) the sections of the split-nut are longitudinally slidably engaged with each other; 2) the split-nut comprises tool engaging means; 3) the flanged ball-and-socket nut assembly further comprises a sleeve interposed the socket and the split-nut; 4) an outer portion of the sleeve engages the interior of the socket and the split-nut is disposed within a bore in the sleeve; and/or 5) the socket is a compression tower.

Another embodiment of the pivot wing bolt tissue-tensioning assembly comprises:

30 a threaded shaft having a head comprising a wing mount;

a single wing having an aperture engaged with the wing mount such that the wing is rotatably mounted on the wing mount; and

a swing stop that limits the rotation of the wing from a first position approximating parallel to the linear axis of the threaded shaft to a second position approximating normal to the linear axis

of the threaded shaft;

wherein:

the linear axis of the wing is alignable with the linear axis of the threaded shaft; and

the swing stop limits the rotation of the wing about the wing mount to less than one revolution.

Other specific embodiments of the pivot wing bolt tissue-tensioning assembly include those

wherein: 1) the swing stop is integral with the wing; and/or 2) the swing stop is integral with the head of the threaded shaft.

Another embodiment of the split-nut assembly comprises:

two or more nut sections which form a nut when assembled, the nut having a threaded bore; and section retaining means selected from the group consisting of a band, a socket, and a combination

thereof;

wherein the nut sections are spaced from one another a first distance when the section retaining means is engaged with a first portion of the split-nut and in closer proximity or in contact with one

another when the section retaining means is engaged with a second portion of the split-nut; and

wherein the sections of the split-nut are detached from one another or attached to each other by way of a living hinge.

Other specific embodiments of the split-nut assembly include those wherein: 1) the nut comprises a first annular groove having a first diameter, and a second annular groove having a second diameter, wherein the second diameter is larger than the first diameter and smaller than the widest diameter of the nut, and the section retaining means is engageable with the annular grooves of

the nut; 2) the section engaging means is a band disposed in either of the first and second grooves to keep the two or more nut sections in assembly; 3) the section retaining means is a socket having a first larger diameter inner portion, and a second smaller diameter inner portion; and/or 4) the nut comprises a first annular portion having a longitudinally graded diameter and a longitudinally adjacent second annular portion having a longitudinally graded diameter, wherein the larger diameter

portion of the second annular portion abuts the smaller diameter portion of the first annular portion,

and wherein the section retaining means is a band that is engageable with the first and second annular portions of the nut.

Other features, advantages and embodiments of the invention will be apparent to those skilled in the art by the following description, accompanying examples and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are part of the present specification and are included to further demonstrate certain aspects of the invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of the specific embodiments presented herein.

A. INTERLOCKING NUT - where the sections of the split-nut interlock.

FIGURE 1 depicts a front elevation view of a shaft sitting in the cup.

FIGURE 2 depicts a sectional side view of the cup with a side elevation of the shaft.

FIGURE 2a is an inset depicting the threads in circle mm of FIG. 2.

FIGURE 3 depicts top plan view of the interlocking nut along lines B-B of FIG. 4.

FIGURE 4 depicts a side elevation view of the interlocking nut of FIG. 3 with the two sections distended or spaced-apart.

FIGURE 5 depicts a sectional side view of the interlocking nut along lines C-C of FIG. 3.

FIGURE 6 depicts a top plan view of a rotation (driving, tightening or installation) tool, along lines D-D of FIG. 7.

FIGURE 7 depicts a side elevation view of the rotation tool of FIG. 6.

FIGURE 8 depicts a partial top plan view of the interlocking nut and socket and a sectional view of the threaded shaft along lines E-E of FIG. 9.

FIGURE 9 depicts a partial sectional side view of the interlocking nut and a sectional side view of the cup in a cross section of bone.

FIGURE 10 depicts a partial top plan view of the interlocking nut and socket and a sectional view of the threaded shaft along lines F-F of FIG. 11.

FIGURE 11 depicts a partial sectional side view of the interlocking nut and a sectional side view of the cup in a cross section of bone and a side elevation view of the installation tool.

FIGURE 12 depicts a side elevation view of the interlocking nut and tool and a sectional side view of the cup in a bone, wherein the assembly is shown at two different orientations (incident angles) with respect to the bone.

FIGURE 13 depicts a sectional bottom plan view of the cutting tool along lines G-G of FIG.

5 16.

FIGURE 14 depicts a sectional top plan view of the interlocking nut and socket along lines H-H of FIG. 15 after the sections of the nut have been compressed together by the socket.

FIGURE 15 depicts a side elevation view of the interlocking nut, tool and tension gauge and a sectional side view of the cup installed in a bone.

10 FIGURE 16 depicts a side elevation view of the interlocking nut and cutting tool and a sectional side view of the socket in a bone.

FIGURE 17 depicts a front elevation view of the interlocking nut installed in the knee of a mammal.

15 FIGURE 18 depicts a side elevation view of the interlocking nut and a sectional side view of the cup installed in the knee joint. This figure also depicts a section of threaded shaft and an engaged cutting tool after the shaft has been severed by way of the cutting tool.

B. BANDED NUT - where the sections of the split-nut are encircled by an elastomeric, resilient or elastic band.

20 FIGURE 19 depicts a top plan view of the banded nut along lines K-K of FIG. 20.

FIGURE 20 depicts a side elevation view of the banded nut of FIG. 19.

FIGURE 21 depicts a side elevation view of one section of the banded nut and a sectional side view of the band along lines L-L of FIG. 19.

FIGURE 22 depicts a sectional side view of view of the banded nut along lines J-J of FIG.

25 19.

FIGURE 23 depicts a partial sectional side view the banded nut and a sectional side view of a cup installed in a bone.

FIGURE 24 depicts a partial top plan view of the banded nut along lines M-M of FIG. 23.

30 FIGURE 25 depicts a side elevation view the banded nut and rotational tool and a sectional side view of a cup installed in a bone.

FIGURE 26 depicts the assembly of FIG. 25 except that the threaded shaft and nut shown at two different incident angles with respect to the cup and bone.

FIGURE 27 is not included herein.

FIGURE 28 depicts the assembly of FIG. 25 except that the nut has been collapsed and threaded about the shaft to tension the graft engaged with the tissue retainer. The gauge is used to indirectly measure the tension placed on the graft tissue.

FIGURE 29 depicts a side elevation view of the banded nut and rod and a sectional side view of the cup installed in the knee.

C. ENCASED NUT - where the cup acts as an encasement for the SPLIT-NUT sections and not necessarily a flanged socket.

FIGURE 30 depicts a front elevation view of one of the sections of the encased nut along lines P-P of FIG. 32.

FIGURE 31 depicts a side elevation view of the encased nut sections along lines N-N of FIG. 32.

FIGURE 32 depicts a top plan view of the encased nut sections.

FIGURE 33 depicts a sectional side view of the encased nut sections along lines O-O of FIG. 32.

FIGURE 34 depicts a front elevation view of a shaft and cup assembly placed on the surface and within a bone.

FIGURE 35 depicts a sectional front view of the encasement along lines S-S of FIG. 37.

FIGURE 36 depicts a sectional side view of the encasement along lines R-R of FIG. 37.

FIGURE 37 depicts a top plan view of an encasement within which a split-nut of the invention can be placed.

FIGURE 38 depicts a side elevation view of the threaded rod and a sectional side view of a cup along lines Q-Q of FIG. 34 installed in a bone.

FIGURE 39 depicts a partial cross section of the encased nut, a sectional side view of the encasement and a sectional side view of the cup installed in the bone.

FIGURE 40 depicts a partial top plan view of the encased nut along lines T-T of FIG. 39.

FIGURE 41 depicts a side elevation view of the encased nut and driving tool and a sectional side view of the encasement, cup and bone.

FIGURE 42 depicts a partial top plan view of the encased nut along lines U-U of FIG. 41.

FIGURE 43 is not included herein.

5 FIGURE 44 depicts a top plan view of the encased nut along lines V-V of FIG. 45. However, the nut is shown in two different laterally displaced positions with respect to the encasement.

FIGURE 45 depicts a side elevation view of the split-nut, shaft and driving tool and a sectional side view of the encasement, cup and bone.

10 FIGURE 46 depicts the assembly of FIG. 45 except that the nut has been collapsed with the encasement and threaded about the shaft to tension the engaged biological tissue.

FIGURE 47 is not included herein.

FIGURE 48 depicts the assembly of FIG. 45 after installation into the joint of a mammal.

15 D. SIDE PIVOT WING BOLT- where the rod has a single pin on one side to which the wing is secured.

FIGURE 49 depicts a side elevation view of the side pivot wing bolt assembly.

FIGURE 50 depicts a sectional side view of the assembly along lines Y-Y of FIG. 49.

FIGURE 51 depicts a sectional side view of the assembly along lines W-W of FIG. 49.

FIGURE 52 depicts a side elevation view of the assembly of FIG. 49.

20 FIGURE 53 depicts a top plan view of the assembly along lines Z-Z of FIG. 56.

FIGURE 54 depicts a side elevation view of the wing of FIG. 56.

FIGURE 55 depicts a side elevation view of the assembly of FIG. 56 except that the wing is being deployed by the deployment tool depicted in a side elevation view as well.

25 FIGURE 56 depicts a side elevation view of the assembly of FIG. 55 except that the wing has been completely deployed by the tool.

E. COMPRESSION TOWER ASSEMBLY- a specific embodiment of the cup (socket) that allows removal of the hardware without additional surgery.

30 FIGURE 57 depicts a top plan view of a compression tower and banded-nut and a sectional top plan view of an engaged threaded shaft along lines rr-rr of FIG. 58.

FIGURE 58 depicts a side elevation view of a banded nut and side pivot wing bolt assembly and a sectional side elevation view of a compression tower after the entire assembly has been installed.

FIGURE 59 depicts a side elevation view of the compression tower of FIG. 58.

5 FIGURE 60 depicts a sectional side elevation view of the compression tower of FIG. 58.

FIGURE 61 depicts a sectional side elevation view of a bone compression assembly being installed in a fractured elbow.

FIGURE 62 depicts a side elevation view of prior art devices used to reduce a fractured elbow.

10 F. HOLLOW ROD - where the rod has a channel for the delivery of a substance.

FIG. 63 depicts a sectional side elevation view of the bone compression assembly of FIG. 58 after is has been installed in a fractured elbow. The threaded shaft has a bore throughout it length to permit delivery of a degrading material to the site where the wing of the assembly is installed.

15 FIGURE 64 depicts a sectional side elevation view of the assembly of FIG. 63 except that it is being removed from the bone once the bone has healed and the wings have degraded sufficiently that they are no longer strongly attached to the threaded shaft.

FIGURE 65 is not included herein.

20 G. SWING PIVOT WING BOLT- where the wing can rotate at least or approximately 180 degrees in a transverse direction with respect to the linear axis of the threaded shaft.

FIGURE 66 depicts a rear elevation view of the swing pivot wing bolt of FIG. 67 wherein the wing is shown in sectional view along lines c-c.

FIGURE 67 depicts a side elevation view of the swing pivot wing bolt wherein the wing has been deployed transversely to about normal with respect to the linear axis of the shaft.

25 FIGURE 68 depicts a side elevation view of an installation/deployment tool.

FIGURE 69 depicts a top plan view of the tool along lines a-a of FIG. 68.

FIGURE 70 depicts a sectional rear view the swing pivot wing bolt along line b-b of FIG. 67.

FIGURE 71 depicts a side elevation view of the swing pivot wing bolt assembly and deployment tool and a sectional view of a fractured femur in which the assembly in being installed.

FIGURE 72 depicts a sectional side elevation view of the assembly of FIG. 71 except that the deployment tool has been rotated to begin deployment of the wing in the bone.

FIGURE 73 depicts a sectional side elevation view of the assembly of FIG. 72 except that the deployment tool is deploying the wing.

5 FIGURE 74 depicts a sectional side elevation view of the assembly of FIG. 73 except that the wing is even further deployed.

FIGURE 75 depicts a sectional side elevation view of the assembly of FIG. 74 except that the tool has been rotated back to its original position.

10 FIGURE 76 depicts a sectional side elevation view of the assembly of FIG. 75 except that the wing is fully deployed in the femur.

FIGURE 77 depicts a sectional side elevation view of the assembly of FIG. 76 except that the assembly has been pulled in a direction opposite its installation direction such that the wings engage the inner surface of the femur.

15 H. ENCASED SPLIT-NUT METHOD FOR REDUCING A FRACTURED FEMUR.

This embodiment can be used with all of the various pivot wing bolt embodiments described herein.

20 FIGURE 78 depicts a sectional side elevation view of an encased nut assembly comprising a split-nut and an associated flanged cup or encasement installed in one end of the femur, which is also depicted in sectional view.

FIGURES 78b-78d depict a sectional side elevation view of the encasement and a side elevation view of the split-nut of FIG. 78 except that the split-nut is shown in various different stages of installation into the encasement.

25 FIGURE 79 depicts the assembly of FIG. 78 installed in a countersunk bore at one end of the femur before the sections of the split-nut have been collapsed.

FIGURE 80 depicts the assembly of FIG. 79 except that the split-nut has been collapsed.

FIGURE 81 depicts the assembly of FIG. 80 except that a gauge is used to measure the amount of compression being applied by the assembly to the fractured femur.

FIGURE 82 depicts the assembly of FIG. 81 in combination with a cutting tool that severs the excess length of threaded shaft after the proper amount of compression is being applied onto the femur by the assembly.

5 FIGURE 83 depicts the assembly of FIG. 82 after completion of its installation into the femur.

FIGURE 83b depicts a partial sectional side elevation view an alternate embodiment of the encasement nut assembly comprising an encasement band (shown in section), rather than an encasement cup, and a split-nut. The assembly is shown with the sections of the split-nut spaced apart.

10 FIGURE 83c depicts the assembly of FIG. 83b except that the sections of the split-nut are being compressed by the encasement band and a portion of the split-nut is disposed within a countersunk bore in a bone.

I. HINGED SPLIT-NUT - where the Split-nut sections are partially joined by a living hing,
15 resilient or pliable material, hinge or other such engagement.

FIGURE 84 depicts a top plan view of the hinged split-nut along lines M-M of FIG. 85.

FIGURE 85 depicts a side elevation view of the hinged split-nut of FIG. 84.

FIGURE 86 depicts a sectional front view of the hinged split-nut along lines N-N of FIG. 84.

20 FIGURE 87 depicts a partial sectional view of a hinged split-nut installed in a flanged cup (depicted in section) and a bone. The cup has an inner bore having two different sections: one section with a larger diameter and the other section with a smaller diameter.

FIGURE 88 depicts the assembly of FIG. 87 except that the hinged split-nut has been engaged with and collapsed by the socket. The driving tool is being used to thread the nut about the threaded shaft.

25 FIGURE 89 depicts the assembly of FIG. 88 except that the threaded shaft, hinged split-nut, gauge and driving tool are shown at two different incident angles with respect to the bone.

FIGURE 90 depicts the assembly of FIG. 89 except that the excess length of shaft has been cut off.

J. STOP PIVOT WING- where the pivot wing is held at an oblique angle with respect to the
30 rod by a vertical ledge in the pivot wing.

FIGURE 91 depicts a partial sectional side view of a stop pivot wing bolt, wherein the wing is shown in section and at an angle approximately normal to the linear axis of the shaft.

FIGURE 92 depicts the pivot wing bolt of FIG. 91 except that the wing is at an angle approximately parallel to the linear axis of the shaft.

5 FIGURE 93 depicts a rear sectional elevation view of the pivot wing bolt of FIG. 91.

FIGURE 94 depicts a side elevation view of the pivot wing bolt of FIG. 91.

FIGURE 95 depicts a top plan view of the pivot wing along lines g-g of FIG. 94.

FIGURE 96 depicts a sectional side elevation view of the pivot wing along lines h-h of FIG. 95.

10 FIGURE 97 depicts a side elevation view of a stop pivot wing bolt assembly and installation/deployment tool installed within a bone shown in section.

FIGURE 98 depicts the assembly of FIG. 97 except that the tool has been rotated to effect initial deployment of the pivot wing.

15 FIGURE 99 depicts the assembly of FIG. 98 except that the shaft has been pulled partial out of the bore in the bone thereby causing both ends of the pivot wing to engage the surface of the bore.

FIGURE 100 depicts the assembly of FIG. 99 except that the shaft has been pulled out of the bore a sufficient amount to effect complete deployment of the wing, e.g., until the wing is about normal to the axis of the shaft.

20 FIGURE 101 depicts the assembly of FIG. 100 except that a flanged curved socket is being installed at one end of the shaft.

FIGURE 102 depicts the assembly of FIG. 101 except that a rounded or curved nut is engaged with the shaft.

25 FIGURE 103 depicts the assembly of FIG. 102 except that the nut has been engaged with the socket and threaded about the shaft a sufficient amount to provide the desired amount of compression to the fractured bone. This assembly also includes a cutting tools that cuts the excess length of shaft.

FIGURE 104 depicts the assembly of FIG. 103 during cutting of the shaft with the cutting tool.

K. STOP ROD PIVOT WING BOLT- where the pin hinge of the shaft is located off-center to the longitudinal axis of the bolt such that head of the bolt engages the pivot wing and maintains the pivot wing at an oblique angle with respect to the longitudinal axis of the bolt.

FIGURE 105 depicts a partial sectional side elevation view of the stop rod pivot wing bolt assembly comprising a pivot wing and a bolt that are engaged to one another by a hinge located transversely off the linear axis of the bolt.

FIGURE 106 depicts a rear elevation view of the assembly along lines s-s of FIG. 105.

FIGURE 107 depicts a front sectional elevation view of the assembly of FIG. 106.

FIGURE 108 depicts the assembly of FIG. 105 except that the wing is disposed about parallel to the linear axis of the bolt.

L. AXLE ROD - where the rod has two posts with a transverse beam, serving as the hinge, in between.

FIGURE 109 depicts a front elevation view of the assembly of FIG. 108 except that a different hinge is being used.

FIGURE 110 depicts a sectional side view of the assembly of FIG. 109.

FIGURE 111 depicts an opposite sectional side elevation view of the assembly of FIG. 110.

FIGURE 112 depicts a side elevation view of the assembly of FIG. 110 except that an installation/deployment tool is engaged with pivot wing and shaft.

FIGURE 113 depicts a partial sectional front elevation view along lines u-u of FIG. 110.

FIGURE 114 depicts a front view of the assembly of FIG. 110 along lines t-t.

FIGURE 115 depicts a rear view of the assembly of FIG. 110 along lines v-v.

M. AXLE ROD WITH AXLE RECEPTACLE where the assembly comprises a pivot wing and a rod, wherein the rod comprises two connected posts (extended members) and connected by at least two transverse beam such that at least one post is disposed at each (opposite) end of the extended member and one of the transverse beams serves as a pivot hinge at one end and the other transverse beams serves as a ligament fastener bar at the other end of the extended members.

FIGURE 116 depicts a side elevation view of an axle rod assembly and an engaged ligament installed in a bone shown in section.

FIGURE 117 depicts a front elevation view of the assembly of FIG. 116.

N. SUTURE NUT - a banded split-nut having an internal friction surface instead of threads and a relatively non-elastomeric band that engages the surface of the sections of the split-nut.

FIGURE 118 depicts a top plan view of the ring of the suture nut.

5 FIGURE 119 depicts a top plan view of the suture nut comprising two nut sections and the ring of FIG. 118.

FIGURE 120 depicts a side elevation view of the suture nut of FIG. 119 except that the ring, which has a graded inner and optionally outer diameter, is disposed on a lower of two longitudinal sections of the split-nut. The longitudinal sections have a graded outer diameter such that the larger
10 diameter portion of the lower section abuts the smaller diameter portion of the upper section. Overall, the upper section has a larger diameter than the lower section.

FIGURE 121 depicts the assembly of FIG. 120 except that the ring is shown in section along line w-w of FIG. 119 and the two halves of the split-nut are spaced from one another as they loosely
15 a suture.

FIGURE 122 depicts a sectional front elevation view along line y-y of the assembly of FIG.
119.

FIGURE 123 depicts another sectional view of the suture nut.

FIGURE 124 depicts the assembly of FIG. 120 wherein the ring is being moved longitudinally from the lower longitudinal portion of split-nut toward its upper longitudinal portion.

20 FIGURE 125 depicts the assembly of FIG. 124 except that the ring has been moved even further up.

FIGURE 126 depicts a partial sectional view of the assembly of FIG. 125.

FIGURE 127 depicts the assembly of FIG. 126 except that the ring has been moved even further up.

25 FIGURE 128 depicts a side elevation view of the assembly of FIG. 127.

FIGURE 129 depicts the assembly of FIG. 128 except that the ring is now fully engaged with the upper longitudinal larger diameter section of the split-nut such that the halves of the split-nut are in contact with one another and the split-nut engages the suture tightly.

FIGURE 130 depicts a partial sectional side view of the assembly of FIG. 129.

30 FIGURE 131 depicts a top plan view of the assembly of FIG. 129.

O. TRANSVERSE IMPACTION SCREW – wherein the screw comprises a flat surface on a rod such that when the rod is rotated about its linear axis a change in the position of a tissue engaged with the rod is affected.

5 FIGURE 132 depicts a top plan view of the transverse impaction screw along lines H-H of FIG. 133.

FIGURE 133 depicts a side elevation view of a transverse impaction screw having a flat rod portion, a tool-engaging means at one end and a threaded shaft portion interposed the flat rod portion and the tool-engaging means.

10 FIGURE 134 depicts a partial front elevation view of the screw of FIG. 133 along lines J-J.

FIGURE 135 depicts a rear elevation view of the screw along lines G-G of FIG. 133.

FIGURE 136 depicts a partial sectional front view of the transverse impaction screw as installed in a bone such that the flat rod portion of the screw is disposed within a bore in the bone (shown in section) and engaged with a biological tissue, such as a ligament or tendon.

15 FIGURE 137 depicts a side elevation view of the screw, bone and ligament of FIG. 136 wherein the bone is shown in section.

FIGURE 138 depicts the screw, bone and ligament of FIG. 136 except that the flat surface of the flat rod is disposed transverse rather than parallel to the linear axis bore in the bone.

20 FIGURE 139 depicts the screw, bone and ligament of FIG. 137 except that the short (horizontal) axis of the flat surface of the flat rod portion is disposed transverse or about normal to the linear axis of the bore in the bone.

FIGURE 140 depicts a perspective view of ligament graft engaged with two tissue-retainers according to the invention. The ligament graft forms a double loop.

25 FIGURE 141 depicts the ligament graft of FIG. 140 except that the two ends of the graft are sutured together.

FIGURE 142 depicts the ligament graft of FIG. 141 except that a portion of the adjacent longitudinal edges of the loops of the ligament graft are sutured to each other.

30 FIGURE 143 depicts the ligament graft of FIG. 142 except that the loops of the ligament graft have been sutured to each other approximately along their entire length. The loop portions disposed within the tissue retainers may or may not be sutured to each other.

DETAILED DESCRIPTION OF THE INVENTION

Although specific embodiments of the invention will now be described with reference to the drawings, it should be understood that such embodiments are by way of example only and are merely illustrative of but a small number of the many possible specific embodiments to which the principles of the invention may be applied. Various changes and modifications obvious to one skilled in the art to which the invention pertains are deemed to be within the spirit, scope and contemplation of the invention as further defined in the claims.

The Interlocking Split-nut - Figures 1-18

Figure 1 depicts the open end of the cup 93, the threaded shaft 12 engaged with the cup and with the ligament graft 27 through the eye 15 of the threaded shaft. Figure 2 depicts the threaded shaft 12 with threads 8 and eye section 15 attached to ligament graft 27 disposed within the cup 93 (in section) along line A-A. The cup includes a circumferential flange 91 and an inner surface 92 defining a bore in the cup. The bore has two differently-sized sections. The first section proximal to the flange has a larger diameter, and the second section distal from the flange has a smaller diameter. A shoulder region between the first and second sections can have a graded diameter.

Figure 2a depicts an inset m-m of the encircled portion from Figure 2. The inset depicts the buttress threads 8 of the threaded shaft 12. These threads 8 have a slope 89 that is short and perpendicular, or about perpendicular, to the linear axis of the shaft 12. The slope 88 is long and disposed at an obtuse angle relative to the shaft 12. While these threads 8, referred to as buttress threads, can be regular threads, the preferred embodiment for the threads, when used with a split-nut such 36, are as depicted in Figure 2a.

Figure 3 depicts a top plan view of the interlocking split-nut 36. It has two sections 1, 3 that form a generally donut-shaped nut 36. The tabs 20 and 21 located on section 3 mate with and engage the depressions 21a and 20a in section 1, thereby maintaining the two sections of the split-nut together but in slidable relation to each other. The internal threads 61 are located within the bore 60 of the split-nut. The threads may or may not cover the entire surface defining the bore 60. The split-nut also includes driving tool-engaging means 22 and 23 that may be female or male engaging means. As depicted, the tool-engaging means are receptacles or recesses that can engage a screwdriver or driving tool 63, depicted in Figure 7. The two sections 1 and 3 are distended, or

spaced apart, from each other so that if the shaft 12 of Figure 1 were disposed within the bore 60, the split-nut would be able to slide longitudinally along the shaft length without having to be turned.

Figure 4 depicts that split-nut 36 with an optionally arcuate outer circumferential surface.

In figure 5, the threads 61 on section 3 preferably do not span the entire 180 degrees surface of the inside diameter of the section. This permits the sliding of the spaced-apart split-nut along the length of the shaft. If the threads were to extend the full 180 degrees, the threads on the sides would not ratchet away from the shaft 12, preventing the buttress thread from sliding forward.

The screwdriver 63 depicted in figures 6 and 7 is a round and hollow cylinder that fits over the shaft, 12. The two prongs (male nut-engaging means) 64 and 65 enter the two slots 22 and 23 in the split-nut and serve to push the nut linearly forward on the threaded shaft 12. When the sections, 1 and 3 are in the collapsed position, due to an external force such as the force of cup wall 92, the threads 60 and 61 are in direct contact with the threads 8 of the shaft 12. As described later, the screwdriver 63 can also be used to turn the nut so that it rotates about the shaft 12.

Figure 8 depicts the split-nut 36 superposing the socket 93 and engaged with the threaded shaft 12 (shown in section). The threaded shaft 12 is shown in cross section and the threads, 60, 61, are loose against the thread 8 of the shaft 12.

Figure 9 depicts the assembly of Figure 8, wherein the threaded shaft 12 passes through the cup 93 and into a bore 53 in a cross section of bone 51. The bore 53 has been drilled through the bone 51. The eye (or tissue retainer) 15 of the threaded shaft 12 is disposed within the bore 53 and engaged with the ligament graft 27. The split-nut is shown in partial cross section with half of section 1 cut away so that the threads, 61 of section 1 is depicted as well as the slot 23 for a prong 64 of the screwdriver 63.

The threads 61 of section 1 have short slope 89a and long slope 88a that are complementary to long slope 89 and short slope 88 of the threads 8 of the shaft 12. As the long slope 89a of section 1 passes the long slope 89 of shaft 12, section 1, is pushed radially outward from the longitudinal axis of shaft 12. As the slope 89a of section 1 passes the long slope 89 of shaft 12, short slope 88a of section 1 comes in contact with short slope 88 of shaft 12 and section 1 moves radially inward to the longitudinal axis of shaft 12.

Each time the split-nut 36 passes the long slope 89 of the shaft 12, it moves slowly outward. As the split-nut passes each short slope thread 88 of the shaft 12, it moves rapidly inward thereby

affecting a ratchet-type of motion. Until the section 1 and 3 of the split-nut are pushed by an outside force toward the shaft 12, the split-nut 36 can move toward the eye 15 of the shaft 12 in this ratcheting motion.

Because there is no force that keeps the sections 1 and 3 distended, they do not tend to stay distended so that they are prohibited, by the action of the short slope 89 of the buttress threads, from sliding away from the eye 15. This sliding motion can continue as long as the two sections 1 and 3 of the nut 36 are allowed to distend in the wider diameter section of the cup 93, prior to coming in contact with the smaller diameter section of the cup 93.

Figure 10 depicts the assembly of Figures 8 and 9, except that the sections 1 and 3 of the split-nut are no longer spaced apart any significant distance. Therefore the threads of the shaft are fully engaged with the threads of the split-nut. At this point, the screwdriver 63 must be utilized to rotate the split-nut and drive it forward, as it will only move forward by rotation about the shaft.

Figure 11 depicts the sections 1 and 3 as they come into contact with the smaller diameter section of the bore 92 of the cup. The sections are compressed toward each other so that the threads 61 and 60 compress against the threads 8 of the shaft 12. The prongs 64 and 65 of the screwdriver are shown engaged with the mating slots 22 and 23. The split-nut 36 is rotated until it contacts the most distal end of the socket, i.e., the end nearest the tissue retainer of the shaft, so that the sections 1 and 3 are fully compressed against the shaft 12 and the nut 36 cannot move by ratcheting within the cup 93.

The cup 93 is stabilized against the outer surface of the bone by way of the flange. The cup actually sits within the countersink of the countersunk bore 53. As note in Figure 12, the shaft and split-nut assembly generally have a ball-and-socket configuration. This swivel action of the nut 36 in the cup 93 is important because the bore 53 may be drilled at a less than optimal angle. In the diagram, this is shown by bores 53b and 53a within the bone 51. This swivel is a result of curved surface 92a of the nut 36 that abuts against curved surface of the cup 93 at its most distal end. If there were not this ability to swivel, the eye 15 can be pulled laterally away from the longitudinal axis of the threaded shaft 12, when the bore 53b is drilled at this non-optimal angle, causing undue stress on the shaft 12. The shaft 12 would tend to bend at the eye 15, since the cup 93 would hold the hinged split-nut 36 stationary while the shaft 12 would be pulled from a different direction. Also note that the screwdriver 63 has a smaller distance between the two prongs 64 and 65, than is the distance

between the receptacles of the nut 36, so that the screwdriver it will not block the nut 36 from swiveling in the curved 92a section of the cup 93.

Figure 14 depicts the sections 1 and 3 compressed against each other and against the threaded shaft 12. The prongs, 64 and 65 are shown in cross section inside the grooves 22, 23 of the split-nut 36. The cup, 93, is shown in cross section at narrow section 92 demonstrating that there is almost no space between the walls 92 of the cup and the nut 36 sections, 1 and 3.

Figures 14 and 15 depict the split-nut assembly almost completely installed. The sections of the split-nut are in close contact with one another as they are being forced against each other by the inner surface of the bore in the socket. The proximal end of the ligament graft 27 is attached to one end to the eye 15, while the distal end (not shown) of the ligament graft extends toward the other end of the bore 53. Further rotation of the nut 36 causes the eye 15 of the threaded rod 12 to move toward the cup 93 and pull on (apply tension to) the ligament graft 27. Further clockwise rotation of the nut 36 causes further tensioning of the ligament 27. Counterclockwise rotation of the nut 36 causes the ligament 27 to loosen. A gauge 82 attached to the threaded shaft 12 measures the tension in the ligament graft 27.

By pulling the gauge 82 away from the cup 93, the gauge can register the tension force that is placed on the ligament graft 27. After pulling on the gauge, the nut 36 is pulled slightly out of the cup section 92. The nut 36 is then tightened while the gauge registers the tension force, until the nut 36 sits in the cup 93. The bone is then put through range of motion, by rotating it against the nearest bone at the nearest joint, and the ligament graft 27 is allowed to stretch and acclimate to its new environment through the movement. The gauge 82 is then pulled away from the cup to the proper tension level and the nut 36 is then tightened until it makes contact with the cup 92. When the tension appears to be stable, the nut 36 can be loosened one time and the gauge 82 is pulled at the proper tension and the nut 36 is tightened one final time as it sets within the cup 92. In this fashion, precision tension is applied to the ligament 27.

Alternatively, the tension placed upon the ligament could be measured by measuring the compressive force between the outer surface of the nut and the inner surface of the socket. A compressive-force measuring cell would be placed between the nut 36 and the cup walls 92. The nut would then be tightened until it the proper compression force registers on the measuring device.

Figures 16 depicts the split-nut 36 installed within the cup 93 wherein the gauge 82 has been removed after the ligament graft 27 has depicted that it is stable at the proper tension level. Figures 13 and 16 depict the scoring (cutting) tool 73 placed about and rotated around the shaft 12 while the lever 73a is pulled in direction p so that the cutting tooth 71 is held against the shaft 12 with pressure and cuts into the shaft 12 with score 80 around the shaft 12. Once the shaft 12, is fully scored 80, the shaft beyond the score 80 is broken off by pulling lever 73a sharply, away from the shaft 12, in direction p. The result of this action is depicted in figure 18, with the excess shaft, along with the scoring tool, 73, being taken away from the cup 93. An alternative cutting means, instead of a scoring tool 73 that is rotated around the shaft, would be large wire cutter that is used to cut the shaft 12, beyond the nut 36. Still another cutting means would be a shearing tool that shears the shaft 12 beyond the nut 36.

A close up of the cutting tool 73 and the cut length of shaft 12 at score 80 along lines G-G is shown in Figure 23. The cutting tooth is shown cutting into the shaft 12, shown in cross section so that the shaft 12, is scored 80.

A view of the knee, made up of the tibia 51, femur 52 and an outline of the patella 70, is shown in figure 17. The nut 36 is sitting inside the cup 93. The patella has been removed and is shown in outline 70. The ligament graft 27 is also shown in ghost lines inside the bore 51 and 52, also shown in ghost lines. The graft 27 passes from the tibia 51 to the femur 52 where, also shown in ghost lines is a fastener 52c that serves to hold the end of the graft 27 opposite the eye 15, in the femur 52.

Figure 18 further depicts the tibia 51 in full cross section and femur 52 in partial cross section with the ligament graft 27 traversing the bore 53 in the tibia and going into a bore into the femur 52. The ligament graft 27, as pictured, is constructed to duplicate the Anterior Cruciate Ligament that has been ripped and must be replaced. The kneecap, 70, is shown in cross section. The cup 93 is shown in cross section with the nut 36 fully seated in the cup 93 and the shaft 12, cut nearly flush to the nut 36. The ligament graft, 27, by virtue of the rotation of the nut 36 on the threaded shaft 12, has tightened the ligament graft 27 to the optimal level. The ligament 27 keeps the bones 51 and 52 stable against each other with proper pressure so that the patient has a stable knee.

The Banded Split-nut - figures 19 – 28.

The banded split-nut 46 depicted in figures 19-22. The split-nut has two sections 2 and 4 distended (spaced apart) from each other. The band 5 is elastomeric (resilient or elastic) in nature and is shown in the stretched position due to the distension of the section 2 and 4. The threads 61 of section 4 partially cover the 180 degrees of the inside diameter. Slots 22 and 23 are adapted to receive the screwdriver prongs 54 and 65 of screwdriver 63.

Figure 20 depicts a side view of the split-nut 46. The banded split-nut 46, in the distended position, is depicted in figure 22 with sections 2 and 4 in cross section, along lines J-J of figure 19. The band 5 is also shown in cross section.

A view of section 4 with the slot 23 is depicted in figure 21, with the band 5 cut along lines L-L of figure 19. The threads 61 of the banded split-nut 46 do not extend the full 180-degree curvature of the inside diameter of the nut 46. This is to allow the two sections, 2 and 4, to expand and contract along a threaded shaft as they move linearly forward on the shaft toward the eye 15.

In figure 23, the banded Split-nut 46 is shown sliding longitudinally forward on the threaded shaft 12. Since the band 5 is elastic, the threads of sections 2 and 4 continually hug the threads 8 of the shaft 12. The threads 61 of section 4 have short slope 89a and long slope 88a that are reciprocal to long slope 89 and short slope 88 of the threads 8 of the shaft 12. As long slope 89a of section 4 passes the long slope 89 of shaft 12, section 4, is pushed radially outward from the longitudinal axis of shaft 12. As slope 89a of section 4 has passed long slope 89 of shaft 12, short slope 88a of section 4 comes in contact with short slope 88 of shaft 12 and section 4 moves radially inward to the longitudinal axis of shaft 12. As the split-nut 46 passes the long slope 89 of the shaft 12, it moves slowly outward. As the split-nut passes each short slope thread 88 of the shaft 12, it moves rapidly inward. Until the section 4 and 3 of the split-nut are pushed by an outside force toward the shaft, 12, the split-nut 46 can move toward the eye 15 of the shaft 12 in this ratcheting motion.

Because band 5 is elastomeric, sections 2 and 4 do not stay distended after slope 89a passes slope 89. Section 4 is prohibited, by the action of the short slope 89 of the buttress threads, from sliding in an opposite direction, away from the eye 15. The ratchet sliding motion toward eye 15 can continue as long as the two sections 2 and 4 of the nut 46 are in the wider diameter section of the cup 93, prior to coming in contact with the smaller diameter section of the bore 92 of the cup 93. Figure 24 depicts a top plan view of the banded split-nut of figure 23.

At this point, the operation of the banded split-nut is similar to that of the split-nut depicted in Figures 8-18. Accordingly, operation of the banded split-nut is depicted in Figures 25-29. In figure 25, the banded split-nut is in the smaller diameter section of the bore 92 of the cup 93 so that the sections 2 and 4 are compressed by the walls of the cup 93. At this stage, there is no room for the sections 2 and 4 to expand outward, so they remain collapsed against the threaded shaft 12. A screwdriver 63 is required to turn the nut 46 so that it moves in a rotational fashion forward into the cup 93. When the nut 46 is seated in the bottom section 92 of the cup, it can swivel in the cup 93 so that if the bore 53b is too high or too low, 53a, the shaft 12 can swivel inside the cup 93, along with the screwdriver.

Due to the rounded and curved surface construction of the banded split-nut, the nut and socket form a ball-and-socket type of joint. Although preferred, it is not necessary for the curved outer surface of split-nut to be complementary to the curved inner surface of the bore. Accordingly, Figure 26 depicts the split-nut and shaft assembly disposed at various incident angles with respect to the surface of the bone, while maintaining the relative incident angle of the socket approximately constant.

Operation of the ball-and-socket assembly of Figure 28 with a tension-measuring gauge is similar to operation of the ball-and-socket assembly of Figure 15. After achieving the precise tension on the ligament graft, the excess length of shaft is cut with a cutting tool (as depicted in Figure 16). Completed installation of the assembly is depicted in Figure 29.

The Encased Split-nut - figures 30-48.

Figures 30-33 depict various different views of an encased split-nut. In figure 32, the two sections 6 and 7 of the split-nut 48 include threads 40 that, however, do not cover the full 360 degrees of the inner surface of the bore of the nut. This incomplete thread coverage permits movement of the section from the collapsed to the distended position. The split-nut comprises external paired radially rounded portions 18a and 19a and paired flat portions 13 and 14. In this embodiment, the individual members of the pairs are opposing.

Figure 30 depicts a front elevation of section 7 along lines P-P with flat sections 13 and 14 and threads 40 that cover only a portion of inside diameter area 40.

Figure 31 depicts a side elevation of the two sections 6 and 7 along lines N-N, with flat surface 14 of section 7 and flat surface 14a of section 6. Note that the encased split-nut has a longitudinally curved outer surface as well. Therefore, the assembled split-nut forms a ball-shaped or about hemispherical nut having two opposing surfaces flattened.

5 Figure 33 depicts the two sections 6 and 7 of the split-nut 48 in cross section along lines O-O. The threads 40 are depicted with their buttress configuration with long slope 88a and short slope 89a. These buttress threads, 40 are reciprocal to those of the threads 8 of the shaft 12, as depicted in figure 34. Also depicted in figure 33 is the side profile of curve 18a of section 6 and curve 19a of section 7. These curves, 18a and 19a, allow the Split-nut 48 to swivel when sitting in a curved
10 encasement 95 with curves 18b and 19b as depicted in cross section R-R of figure 36.

Figure 34 depicts the threaded shaft 12 with its eyelet 15 engaging a ligament graft 27. The shaft passes through the cup 55 and by way of the hole 74. This cup 55 holds the encasement 95, depicted in figures 36 and 37. The encasement comprises inner flat sections 83 and 84 that are complementary to and compress the flat sections 13, 13a, 14 and 14a of the split-nut. These flats
15 cause sections, 6 and 7 rotate around shaft 12 clockwise as the encasement 95 rotates clockwise, and counterclockwise when the encasement 95 is rotated counterclockwise. The rounded sections 18a and 19a of the split-nut fit against rounded casement edge 96 and 97, respectively, depicted in figure 37 when the split-nut 48 is in the upper section of encasement 95. As noted, when the split-nut 48 edges 18a and 19a are against edges 18b and 19b of figure 36, the split-nut 48 can swivel in the
20 encasement 95. Flat wall edge 83 is about parallel to flat wall edge 84. These two flat walls, 84 and 83 cause the split-nut 48 to rotate in the same direction that the encasement 95 rotates. Curves wall edge 97 is opposite curved wall edge 96. These two curved walls allow the split-nut sections 48 to swivel back and forth while sitting in the cup 95.

Figure 36 depicts a cross-section of the encasement 95 along lines R-R of Figure 37. Figure
25 35 depicts a cross-section of the encasement 95 along lines S-S of Figure 37. In this cross section, flat edge 84 is adjacent flat edges 14 and 14a of the sections 6 and 7 respectively. Flat edge 85 is adjacent flat edges 13 and 13a of sections 6 and 7 respectively. As the encasement 95 is rotated clockwise, flat edges 84 and 85 push against the flat edges 14, 14a, 13 and 13a of sections 6 and 7, causing the sections to rotated clockwise. As the encasement 95 is rotated counter clockwise, flat

Docket "BEE 9200"

edges 84 and 85 push against the flat edges 14, 14a, 13 and 13a of sections 6 and 7, causing the sections to rotated counterclockwise.

Figure 38 depicts the threaded shaft 12 placed in a cup 55 that is designed to hold encasement 95 and allow the encasement to rotate either clockwise or counter clockwise. The purpose of cup 55 is to keep the encasement 95 at a specific angle N relative to the bone surface 55a. The threaded shaft 12 and ligament graft 27 are located within a countersunk bore 53 that has been drilled in the bone 51. Cup 55 is particularly important when bone 51 has a soft inner consistency but a hard surface along surface 55a. In this case, cup 55 not only holds the encasement 95 at the proper angle N relative to the bone surface 55a, but also prevents the encasement 95 from working its way into the soft bone. Ballast against sinking in the bone 51 is provided by the greater surface area across the bone surface 55a by the flanged edges 55b and 55c.

The split-nut 48 and the encasement 95 are together referred to as the encased split-nut 201. Operation of the encased split-nut (depicted in Figures 39-48) is different than operation of the previously described embodiments. Figure 39 depicts the encased split-nut 201 placed on shaft 12 with sections 6 and 7 held loosely in register against the threads 8 of the shaft 12. As is noted, the thread 8 of the shaft 12, are buttress in nature, and the thread 40 of the section 7, is a reciprocally threaded buttress thread. At this stage, the encasement 95 is placed on the shaft 12 and pushed into the cup 55. Sections 6 and 7 move forward as they pass each thread of the buttress thread of the shaft in the ratcheting motion previously described. The encased split-nut 201 is pushed up the shaft 12 until it rests inside the cup 55.

A top plan view of the cup 55 along lines T-T of Figure 39 is depicted in figure 40. Note that the sections 6 and 7 can move outward or inward against the shaft as there is room within the encasement 95 for this movement when they are near edges 96 and 97. The top of the split-nut also has optional driving-tool engaging means.

In figures 41 and 42, the torque (driving) tool 136 is a hollow tube with an outside square or rectangular shape. This tool 136 can be placed within the encasement 95 so that its flat sides, 84a and 85a lie against the flat edges 84 and 85 respectively of the encasement 95. As the torque tool, 136 is rotated clockwise, the encasement, 95 rotates clockwise around the threaded shaft 12. As the encasement 95 rotates clockwise around the shaft 12, the threads 40 of the section 6 and those of section 7 rotate around the threads 8 of the threaded shaft 12. As these two sections, 6 and 7 rotate

with the encasement 95, the two sections 6 and 7 move linearly in an upward direction, away from edges 96 and 97 with respect to the encasement 95. With rotation of encasement 95, while in cup 55, the sections 6 and 7 linearly traverse the distance from edges 97 and 96 until they sit in aperture 66. With this type of construction, the driving tool need not directly engage the split-nut; however, Figure 41 depicts optional nut-engaging means at one end of the driving tool. When present, the nut-engaging means could engage the driving tool-engaging means on the upper end of the split-nut.

Figures 44 and 45 depict the encased split-nut after the encasement 95 has fully engaged the cup and more particularly after a peripheral outwardly extending flange on the encasement has engaged an inwardly extending shoulder or seat in the bore of the cup, thereby stopping any further penetration of the encasement into the cup. However, the split-nut can continue to be threaded on the shaft along the length of the shaft. The two sections 6 and 7 are seated at the front 66 aperture of the encasement 95 so that the two sections 6 and 7 are collapsed against the threaded shaft 12 by the narrow walls, 18b and 19b of the encasement 95. The shaft and split-nut maintain their ball-and-socket relationship and swivel action within the encasement 95 as the shaft 12 moves toward and away from the longitudinal axis of the cup 55.

Figure 46 depicts operation of the encasement split-nut with a tension gauge. The sections 6 and 7 are located in the front area 66 of the encasement 95 and a tension gauge 82 is attached to the shaft 12. By pulling on the gauge, 82 in a direction away from the graft 27, the encasement nut 201 is pulled out of the cup 55. The proper tension is placed on the ligament graft 27 and the rotation tool 136 is rotated so that the encasement nut 201 is tightened until it sits in the cup 55. The bone 51 is then put through range of motion with respect to the adjacent bone by moving the intervening joint. The ligament graft 27 is allowed to stretch and acclimate itself through this movement. The gauge 82 is then again pulled away from the cup to the proper tension level so that the encased split-nut 201 pulls slightly out of the cup 55. The rotation tool 136 is again rotated until the Encased Split-nut 201 seats in the cup 55. When the tension appears to be stable and at the precise required level, the Encased Split-nut 201 can be loosened one last time and the gauge 82 is pulled at the proper tension. The Encased Split-nut 201 is then tightened one final time so that it sets within the encasement 95.

An alternative tension measuring means would be to place a load-measuring cell 623 attached to a measuring gauge 624 between the encased split-nut 201 and the cup 55. The pressure of the encased split-nut 201 against the load-measuring cell would give an ongoing reading of the pressure

between the encased split-nut 201 and the cup 55, indicating the exact tension in the ligament graft 27. With such a load cell, loosening of the encased split-nut one final time would not be necessary as the gauge 624 would already indicate the tension within the ligament graft 27.

With the tension in the ligament graft 27 stable and at the correct level, a cutting tool, such as the one depicted in Figure 16 would be used to cut the excess length of shaft. Figure 48 depicts the ligament graft 27 in a tibia 51 and passing through the bore 53 across the joint and into the femur 52 that is shown in partial cross section. The ligament graft 27 is attached to the eye 15 of the threaded shaft 12 that is surrounded by sections 6 and 7 of the nut 201 that is sitting in the encasement 95 that is in turn sitting in the cup 55.

Compression Rod with Side Pin Wing - Figures 49 – 64.

A compression rod with side pin wing 182 is depicted in figures 49-58. The threaded shaft 12 has buttress threads 8, a wing 193 attached to the flat section 35 of the shaft 12 at the pin hinge 105. The cross section of the pin hinge 105 along lines Y-Y of Figure 49 is depicted in figure 50 with the pin hinge 105 integral with flat section 35 and the wing 193 is not shown. Note that flat surface 119a of the pin hinge 105 rests against flat edge 119 of the wing 193 to keep the wing 193 flush against the flat surface 119c of the flat area 35 of the shaft 12. The flat section 35 has a stop 31 that protrudes from the flat section 35 of the shaft 12. This stop 31 is depicted in figure 51, which is a cross section along line W-W of Figure 49. The opposite side of the compression rod as shown in figure 49 is depicted in figure 52. Here the flat section 35, is shown fully, and it is integral and an extension of the shaft 12. Added to the diagram is the pushing (installation) tool 108 that serves to push the wing 193 into position.

The wing 193 is depicted in figure 54 with the pin hinge 105 removed. The hole 64 for the pin hinge 105 is exposed and the shoulder 119 for the pin hinge is depicted. Figure 53 depicts a top plan view of the compression rod of Figure 56. Figure 55 depicts the compression rod 182 with the wing 193 being pushed toward the perpendicular position by the action of the pushing tool 108. The upper edge 191 of tool 108 cams against the curved edge 192 of the wing 193 and then along straight edge 192a, pushing the wing 193 toward the perpendicular position in respect to the shaft 12. The stop 31 serves to keep the wing 193 from rotating past the perpendicular by its action against the adjacent lower edge of the wing, 31a, which is along edge 192a.

The compression rod 182 depicted in figure 58 shows the wing 193 deployed into perpendicular to the shaft 12. The surface 31a is located on the edge 192a and pressed against stop 31 that is located on the flat 35 portion of the shaft 12. Threads 8 on shaft 12 stop at curved surface 12a where the curved edge 192 of the wing 193 was situated when the wing 193 was parallel to the shaft 12.

An additional feature included with the compression rod is a compression tower 119 with prongs 115, 116, 117 and 118 as depicted in figures 59 and 60. The compression tower depicted in figure 60 with the cup 119 being rounded so that the banded split-nut 5 of figure 58, can fit into the cup 119 and can swivel within the cup 119.

If the compression tower's longitudinal axis is not exactly aligned with the longitudinal axis of the shaft 12, the eye 15 can be pulled laterally away from the longitudinal axis of the threaded shaft 12 causing undue stress on the shaft 12, if the compression tower is not present. The shaft 12 would tend to bend as it exits the nut 136, as the cup 93 would hold the split-nut 46 stationary while the shaft 12 would be pulled from a different direction.

The purpose of the compression tower is to keep the fastener, 5, external to the skin so that the entire compression rod assembly can be removed from the bone without making a large incision in the skin for the nut 136 to be removed. This will be depicted in the upcoming diagrams.

Figure 62 depicts an elbow fracture 184 that spans the narrow region of the ulna bone just below the joint, where the ulna joins the humerus 175. A conventional method of fixating (reducing) this fracture is depicted Figure 62. Two thick wires, referred to as Kirschner wires, 198 and 197, are placed through the ulna bone, across the fracture 184. These serve to align the bone portions. A thin stainless steel wire is looped through holes drilled in the bone and tightened to bring the fracture 184 together. The length of the incision 101 is often between five and seven inches and results in a long period of physical therapy to keep the post-surgical scar from inhibiting joint motion.

In figure 63, the compression rod assembly 182 is fully installed within the ulna. The wing 193 is perpendicular to the shaft 12 and abuts against the hard bone surface 336 within the bone of the elbow joint. The wing 193 is kept from rotating past the perpendicular by the action of the stop 31. The compression tower 119 is placed so that the pins 117 and 115 pierce the skin 196 and rest against the bone surface 368 of the below bone 176. In this way, the banded split-nut 136 is held above the level of the skin and can be removed from the shaft 12 without having to make a large skin

incision. After the compression rod assembly 182 is fully installed, the fracture 184 is fully compacted and the nut 136 in the compression tower is fully tightened, the shaft, 12, is cut to size. This feature allows a one-size-fits all fastener bolt thereby providing a savings to a hospital by reducing inventory and storage space and eliminating the need for multiple sizes of fixation rods.

5 In figure 63, the shaft 12 has a channel 189 through it. This channel is used for introducing a catalyst that will help to dissolve the wing 193 when it is manufactured from dissolvable materials. In this fashion, a relatively strong dissolvable material, that tends not to easily dissolve, can be used for the wing 193. After the fracture 184 has healed, the catalyst is introduced through the channel 189 so that it engulfs the wing 193 and causes it to dissolve more rapidly. Additionally, if the shaft
10 12 is manufactured from dissolvable material, the catalyst will cause the rod to dissolve. According to another embodiment, the wing is made of a biodegradable material that is metabolized or degraded over a period of time during which the bone heals.

Figure 64 depicts the compression rod assembly 182 being removed from the bone. After the wing 193 has sufficiently dissolved, the shaft 12 is pulled from the bore 189 so that the wing 193
15 breaks and is left in the bone 176 to further dissolve. The banded split-nut 136 and the compression tower 119 are removed along with the shaft 12 without making a large incision 186 for removal.

Balanced Pivot Wing Assembly of Figures 66-77

In figure 67, the balanced pivot wing assembly 146 includes a pivot wing 145 that pivots and is held against the shaft 12 by the pin hinge 166 that is shown in the longitudinal center of the pivot
20 wing 145. The pivot wing has a bore 147 that together with the pin 166 defines a hinge. The ends of the wing include irregular V-shaped profiles such that one leg of the V is longer than the other.

Figure 66 is a cross section of figure 67 along line b-b. Figure 66 shows that the pivot wing 145 is boat-shaped or U-shaped. Figure 70 demonstrates that the pivot wing 145 rotates around the shaft 12 via pin hinges 166 and 167 that protrude through the walls of the wing.

25 Figure 68 depicts the tool 138 having a beveled end 144. The tool 143, as depicted in figure 69, is a tube that fits around the shaft 12 of the balanced pivot wing assembly.

Figures 71-77 depict the procedure for installation of the balanced pivot wing assembly 146. In figure 71, the beveled end of the tool is shown engaged with V-shaped end 312 of the pivot wing 145. The tool is used to keep the pivot wing parallel to the shaft 12 during installation until the wing

is ready to be deployed into a position that is substantial perpendicular to the shaft 12 as depicted in 67. Note that the apex of the end 312 of the pivot wing 145 does not line up with the center of the pin hinge 166 that holds the pivot wing to the shaft. This design permits the beveled end 144 to maintain the pivot wing 145 parallel to the shaft 12 during insertion in the bore 153 in the bone 151 and subsequently drive the pivot wing into a deployed position.

Figure 71 depicts the pivot wing 145 being held parallel to the shaft 12 by a tool 138 while it is inserted into a bore 153 that has been drilled into the femur 151, thereby preventing the pivot wing 145 from moving in a clockwise rotation around the pin 166. The Pivot wing, 145, is prevented from rotating in the counterclockwise fashion by the action of its boat shape, as depicted in figure 66, as the bottom of the boat 313, comes against the shaft, 12.

In figure 72, the tool has been removed from close contact with the pivot wing 145 and has been rotated 180 degrees around the axis of the shaft 12. In figure 73, the beveled edge 144 of the tool, in its turned around position, is driven against the pivot wing 145 causing it to rotate in a clockwise fashion and deploy into an angle that is oblique with respect to the linear axis of the shaft.

The pivot wing 145, as depicted in figure 74, rotates until its long edge 314 is flush against the end 144 of the tool 138, and the pivot wing 145 is at an oblique angle with respect to the shaft 12. In figure 75, the tool has been rotated about 180 degrees again. The end 144 is used to further coax the pivot wing 145 to the perpendicular position as depicted in figure 76.

When the pivot wing 145 is fully rotated so that the pivot wing 145 is approximately perpendicular to the shaft, the shaft 12 is pulled upward from the bone to impact the pivot wing 145 into the hard bone 124 and 125 on either side of the condyles of the femur 151 (Figure 77). This serves to reduce the fracture 111 of the femur 151 so that the adjacent bones portions contact against each other at the fracture line 111 thereby closing this gap.

With the pivot wing 145 fully impacted into the bone walls, 124 and 125, attention is directed to the opposite end of the shaft 12.

Alternate Encased Split-nut Fastener.

Figures 78-82 describe the use of an alternate embodiment of the encased split-nut fastener with the balanced pivot wing assembly. The encased split-nut 201 can be utilized in a harder bone, such as the femur 151. In this embodiment, the encasement 95 includes shoulders 153c and 153d and

the cup 55 (Figures 39-45) is not required, since the outer surface of the bone provides sufficient ballast to keep the encasement 95 from sinking into the bone during installation of the device. The surfaces 153c and 153d are generally perpendicular to the long axis of the bone 151, so there is no need to use a cup 55 to hold the encasement 95 at a specific angle. The countersink 153a of the countersunk bore 153 is sufficiently large to receive the encasement 95 without the aid of a cup 55; however, the counter sink will generally be smaller in diameter than the circumferential flange comprising the shoulders 153c and 153d.

As depicted in Figure 78, the bone 151 has a countersunk longitudinal bore 153 which has a cup-shaped countersink 153a at the entrance to the bore. This cup shape 153a is designed to receive the encased split-nut fastener 201 with its two sections 6 and 7 that were depicted in figure 32. This Encased split-nut is a securing means that is introduced onto the shaft 12 at the end opposite the pivot wing 145. Note that the encasement 95 inserts directly into the bone 153, rather than into a frame 55 as in Figure 39. The encasement 95 is first slid along the shaft 12 until it sits in the prepared bore in the bone 51 as depicted in figure 79. The encasement 95 is rotated so that the sections 6 and 7 of the split-nut rotate with the encasement and move deep into the encasement as depicted in figure 80.

In figure 81, a force gauge 82 has been placed between the encasement 95 and the bone 151 to measure the amount of compressive force that is exerted on the bone by the combined action of the encased split-nut and the pivot wing assembly. This gauge can also be inserted between the encasement 95 and the sections 6,7 of the split-nut, to register the compressive forces. Based upon the reading of the gauge 82, the fastener 201 can be loosened or tightened until the exact pressure is reached and remains stable.

Figure 83 depicts the pivot wing 145 fully seated against the hard bone 124, 125 and the encased split-nut 201 in the femur 151. Rotating the encasement 95, causes further movement of the shaft so that the pivot wing, 145, exerts pressure on the bone walls, 124, 125, as depicted in figure 83, where the fracture 111 gap has decreased in size. With the bone 51 fully fastened, the shaft 12 can be cut to size. In figure 82, the tool 73 creates a score 80 in the shaft, 12. And as shown previously as in figures 18 and 29, the excess shaft, 12, is snapped off so that the shaft 12, is at the correct length so that it doesn't protrude while it holds the bone 151 together until it heals. Instead of a cutting tool that is rotated around the shaft, a large wire cutter or shearing tool can be utilized.

As in figure 83, further rotation of the encasement, 95, causes the shaft to move upward, causing the pivot wing, 145 to impact into the bone walls, 124, 125. This in turn causes the fracture 111 to reduce in size, and align the bone 151 along the shaft. To prevent friction from developing between the encasement 95 and the bone 151, as the encasement 95 is rotated in the bone, a washer 95 can be provided as an interface between the cup 95 and the bone 151.

The Pivot wing, firmly embedded in the bone 124, 125, helps prevent the bone from twisting at the fracture 111, meaning that the upper half and lower half of the bone will not twist about their linear axes with respect to one another.

The Pivot wing 145, if made of metal, is removed using the tool 138, to rotate the pivot wing 145 it counter clockwise and hold it during removal so that the pivot wing, 145 is parallel to the shaft, 12. Alternatively, if the pivot wing 145 is made of dissolvable material, it will dissolve over time. The shaft 12 can be made with a hollow channel such as channel 226 of figure 63 whereby a catalyst is introduced to cause the pivot wing 145 to dissolve. With the pivot wing, 145, dissolved, the shaft, 12 and the split-nut, 201, can be pulled together out of the bore, 153 in the bone, 151, after healing of the fracture, 111, has occurred. Still another embodiment would have the shaft 11 and pivot wing 145 made of dissolvable materials that would dissolve over time with or without the aid of a catalyst.

The arrangement, where the shaft 12 is metal and the pivot wing 145 is dissolvable, allows the shaft, 12, to withstand the greatest forces along the length of the bone, 151, particularly at the fracture 111 edges. The pivot wing, 145, made from weaker dissolvable material, is not subjected to the forces of those of the shaft, 12, during weight bearing on the limb. Its purpose is merely to provide the proper level of compression between across the fracture 111 line. Hence it can be made of weaker dissolvable polymers.

An alternate embodiment of the encased split-nut assembly is depicted in Figures 83b and 83c. In this embodiment, the encasement is a washer 955. The bone is countersunk with the bore 153 such that the countersink 153e is rounded. The washer is placed over the shaft 12 and then the split-nut is placed over the shaft. The split-nut is then pushed down the length of the shaft and engaged with the washer and the countersink. The encased split-nut assembly so formed could be tightened by rotating the washer, if the washer has driving tool engaging means, or by rotating the split-nut, if the split-nut has driving tool engaging means.

While the balanced pivot wing assembly 145 is used in reducing and fixating the fracture 111 of the femur, other compression rods described herein, having a single wing of almost any design, would work well.

Hinged Split-nut - Figures 84-90.

Figures 84-86 depict a hinged split-nut 46 comprising two sections 2, 4, held together by a living hinge 147. The top plan view, along lines M-M, is shown in figure 84. The hinge comprises a pliable or resilient material. Although a living hinge is depicted, an articulating hinge, where sections 4 and 5 are separate and abut each other or are joined by a rotational hinge connection, could be used as well. The hinged split-nut has ridges 122, 123 that receive a rotation tool. The threads 350 and 350a generally do not extend fully around the inside bore of the nut 147. This allows the sections 4 and 5, when separated, as in figure 85, to slide along the shaft 12 while the threads, 350 and 350a, do not contact the threads 8 of the shaft.

The hinged split-nut is depicted in cross section in figure 86, along lines N-N of Figure 84. The raised ridge 123 engages with a driving tool that turns the hinged split-nut 137. The area where section 4 joins to section five is shown in cross section by hatch areas 147 and 147a.

Operation and installation of the hinged split-nut is very similar to that of the banded split-nut and the split-nut described above. Figure 87 depicts a cross section of bone 51 having a countersunk bore 53. The assembly includes the cup 93 in which is seated the nut 46 and the shaft 12. The shaft has an eye-type of tissue retainer 15 to which the ligament graft 27 is attached. The hinged split-nut 46 slides linearly along the threaded shaft 12 into the cup 93. The nut section 4, is shown in partial cross section so that the threads 350 are visible. The threads 350 of this section do not touch the threads 8 of the shaft 12, so that it moves linearly forward or backward. Alternatively, the angle between the sections 4 and 5 can be reduced so that the nut 46 moves along the shaft 12, toward the eye, with the ratcheting motion described previously.

In figure 88, the hinged split-nut 46 has moved into area 92 of cup 93 where the walls are thicker. The area 92 has a smaller diameter than the area adjacent the flanges of the cup and cause the sections 4, 5 of the hinged split-nut to be compressed together. As in other embodiments described herein, once the sections 4,5, are compressed, the nut can only rotate about the shaft in order to move along the length of the shaft. Sections 4,5 of the hinged split-nut 46 have ridges 122,

123 that engage receptacles in the driving tool 63 depicted. The driving tool 63 is used to rotate the nut 46 clockwise so that it moves linearly toward the eye 15 of the shaft 12 and into the narrow portion 92 of the cup 93.

The hinged split-nut 46 is rotated with the rotation tool 63 about the shaft until, as in Figure 89, it seats in the narrow portion 92, of the cup 93. Here, the sections, 4 and 5 are fully compressed against the threads 8 of the shaft 12. Further rotation of the Hinged Split-nut 46 causes the eye 15 of the shaft 12, to move toward the cup 93 creating more tension on the ligament graft 27 that sits in bore 53, in a cross section of bone 51. The spherical nature of the Hinged Split-nut 46 allows it to swivel within the curved section 92 of the cup 93, so that if the bore 53, is drilled at a skewed angle such as 53a or 53b, the shaft 12 and eye 15, can swivel to accommodate the angle. The rotational tool 63 that has captured ridge 123 and ridge 122 does not impede the swivel action. As the nut 46 swivels, the tool 63 generally does not contact the walls of the cup 93. Were the rotational tool to hinder the swivel action of the nut 46, the shaft 12 would bend at the nut as it assumes a different angel than that of the nut 46.

The tension on the ligament 27 is measured with a gauge 84. The ligament graft 27 tends to stretch out after a few minutes of sitting in the bore 53 or through movement of the adjacent joint through range of motion. The rotation tool 63 is rotated clockwise so the Hinged Split-nut 46 rotates and tightens the ligament graft 27. The operation of the gauge is conducted similar to as described above.

Once the tension on the ligament 27 is stable, the shaft is cut as above. Figure 90 shows a hinged split-nut assembly after completion of installation.

Alternate Stop Pivot Wing Compression Rod - Figures 91-104

Figures 91-96 depict an alternate embodiment of the stop pivot wing compression rod assembly 352. The assembly also employs a boat-shaped or U-shaped pivot wing 146, except that unlike the balance pivot wing 146 that can rotate almost 180 degrees and is held in place by the action of the bone, this assembly has a stop 82 that prevents the pivot wing 146 from rotating past 90 degrees. The pivot wing 146 is depicted in cross-section in figure 91 with the shaft 12, which has threads 8 (not shown). The vertical stop 82 is integral with the pivot wing and rests against the shaft 12, thereby holding the pivot wing at the oblique angle when pressure is placed on tip 56 of the wing.

The pivot wing 146 is depicted in figure 92 in a position that is approximately parallel to the linear axis of the shaft. This is the position used to insert the assembly into a bore.

In figure 93, the shaft 12 is depicted in cross-section to shown the dual pin hinges 166 and 167 that articulate with the pivot wing 146. The pivot wing 146 rotates from the vertical position in figure 92 to the horizontal position in figure 91 and is prevented from rotating any further by the stops 83 and 82. It should be noted that stops 83 and 82 can be manufactured at a variety of different angles so that the pivot wing 146 can be limited in rotation by these stops 82 and 83 to more or less than 90 degrees. This features allows the pivot wing compression rod 352 to be adapted to a variety of environments in the body where the pivot wing must hold the bone with a compressive force at an angle that is oblique to, or different than, 90 degrees.

Figure 94 depicts a side elevation view of the entire pivot wing compression rod 352 with pin hinge 166 shown in the pivot wing. This demonstrates how the rod 352 appears when it is in the deployed position, with the wing 146 configured at 90 degrees with respect to the shaft 12.

Figure 95 depicts a top plan view of the pivot wing 146 without the shaft 12. The pivot wing end 56 is split due to the position of the pivot wing 146 when in the vertical position. The end 56 has two sides 186 and 187 with a space 188 in between. This width of this space 188 approximates but is larger than the diameter of the shaft 12. The stop, 82 that prevents the pivot wing 146 from rotating past the oblique angle, is located behind the pin hinge opposite the end 56.

The cross-section of the pivot wing 146, without the shaft 12, is depicted in figure 96. The wing has a pin hinge hole 166a through which a pin is passed.

Figures 97-104 demonstrate the operation and installation of the stop pivot wing compression rod assembly. The assembly depicted in Figure 97 is inserted into a bore 129 through the bone sections, 114, 215 so that its shaft, 12, spans the fracture 111. The installation tool 511 is used to hold the pivot wing 146 parallel to the shaft 12. Its tip 556 keeps the pivot wing 146 from rotating out of the position in which it is parallel to the shaft 12.

In figure 98, the tool 511 has been rotated 180 degrees around the shaft 12 so that its tip 556 is touching the area of the pivot wing 146 that is near tip 56. The tool is being used to push the tip 56 into the bone 215. At the same time that the tip 56 is pushed, the shaft is pulled outwardly so that the pivot wing 146 rotates into the bone in an upward direction to help the impaction of tip 56 into the bone 215.

The pivot wing continues to rotate toward a perpendicular position as the shaft 12 is pulled upward, as depicted in figure 99. The tip 56 serves as the stable point around which the pivot wing 146 rotates as the shaft 12 is pulled upward in a direction opposite its insertion direction.

Figure 100 depicts the tool 511 being used to stabilize the pivot wing 146 while shaft 12 is pulled upward. The pivot wing has assumed the horizontal position on pin hinge 166 with point 56 embedded in the bone 215 and the end 56a of the pivot wing that is opposite the first end 56 is also embedded in the bone. Whether or not point 56a embeds in the bone, is dependent upon the length of the pivot wing 146, the diameter of the bore 129 and the angle that the pivot wing 146 assumes in relation to the shaft 12. In Figure 100, the pivot wing 146 is held perpendicular to the bone by the action of the stop, 82 as shown previously in figure 91. This allows it to anchor in the bone 215. The assembly is useful in bones where the inside of the bore 129 does not demonstrate architecture. In figure 100, the stop 82 keeps the pivot wing 146 from rotating past 90 degrees.

Solid Spherical Compression Nut – Figures 101 - 104

Figure 101 depicts the just-described stop pivot wing compression rod assembly being used in combination with a ball-and-socket joint. A spherical cup 252 is placed over the shaft at the surface of the bone such that the pivot wing 146 and the spherical cup 252 are at opposite sides of the fracture 111, which separates the two bone portions 215 and 114. The shaft 12 passes through the aperture 353 of the cup 252, while the pivot wing 146 remains in the position that it attained previously.

In figure 102, a solid nut 246, which is another embodiment of the Compression fastener, is threaded onto the shaft. The solid threaded nut 246 has the same spherical shape as the split-nut 36 of figure 9 so that it can swivel in the cup 252 and allow for differences in the angle of the bore 129. However, it does not have the capacity to be applied to the proper position quickly by sliding linearly. Instead, it must be turned on its threads until it reaches the proper position on the threads 8 of the shaft 12. This nut 246 is useful in areas where a shaft 12 of a specific length is used, so that the shaft 12 is made with little excess threaded area. Hence, there is no need to spend a great amount of time turning the nut 246 into place. The nut 246 is rotated on the threads 8 of the shaft 12 until it engages the cup 252 that is now resting against the bone 114.

In figure 103, the nut 246 is shown fully seated in the cup 252. There is compressive force between the nut 246 the pivot wing 146 so that the fracture 111 gap has been closed. As in the embodiment of figure 81, a load cell can be inserted between nut 246 and the cup 146 to measure the compressive force. When the compressive force is stable and at the proper level the shaft 12 is scored with the scoring tool, 316 and then the shaft, in figure 104 is broken at the score 80. The shape of the cup 252 can be deeper to permit placement of the score 80 deeper in the cup 252 so that the score doesn't rub against tissue above it. Although the pivot wing of Figures 101-104 are shown at an angle different than that of Figure 100, it is not necessary that the wing assume this other angle.

Off-Center Pin Stop Compression Rod - Figures 105-108.

In the prior embodiments of the compression rod assembly, the hinge has been located approximately through the transverse center of the shaft, i.e., through the center of the width of the shaft. However, Figures 105-108 depict the off-center pin stop compression rod that includes a pin 342 that is off-center to the longitudinal axis of the shaft 12. The pivot wing 429 is in the deployed position. The stop 420, which is integral with the wing, rests against the end of the shaft 12 along edge 452 so that the pivot wing 429 must stop at a specific oblique angle with respect to the shaft 12.

Figure 106 depicts the pivot wing 429 and the shaft. The pin hinges 346, 345 are seen between the sides (stands) of the boat-shaped (U-shaped) pivot wing and extend from the shaft 12 through the sides of the pivot wing. Note that the shaft is wider than the shaft when viewed from the front. To permit the nut to secure the shaft 12, the threads 8 (not shown) are located on a narrower section of the shaft, which has approximately the same diameter as the shaft 12 of figure 12.

Figure 107 depicts a rear partial sectional view pivot wing and shaft. The pin hinges 346 and 345 are engaged with holes located on the sides of the pivot wing 429.

In figure 108, the pivot wing is in the pre-deployed position with the edge of the stop 420a against the rod 12, so that the pivot wing remains parallel to the shaft 12 during insertion into a bore in a bone. During installation in a bone, the pivot wing 420 is manipulated by way of an installation tool similar to the tool 511 and according to a technique similar to that of figures 97- 100.

Axle Rod Compression rod of Figures 109 - 117

The Axle Rod is another embodiment of a shaft 13 with a single wing 512 that rotates oblique to the shaft 13. However, the pivot wing 512 has a single blade that is not boat-shaped, as

opposed to the boat shape of pivot wing 146 in figure 106. The Axle Rod includes two posts 503, 505 and a transverse beam or axle, 168, serving as the hinge axis. The rod 13 is flat and wide, as depicted in figure 109, and narrow, as depicted in figure 110. The threaded 8a area of the upper portion 13a is a narrower portion where a solid nut 146 or split-nut, 46 can be used for securing this end. The pivot wing 512 has a stop 182, as depicted in figure 110.

The pivot wing and rod are shown in cross section in figure 111, with the shaft 13 corresponding to the post 403. The axle 168 is also shown in cross section as is the pivot wing 512.

Figure 112 depicts the axle rod with the pivot wing 512 in the vertical position. Note that the stop 183 keeps the pivot wing 512 from rotating clockwise past the shaft 13.

Figure 113 depicts a partial sectional front view of the pivot wing 512 along line u-u of figure 110. The stop 183 is shown along the lower portion of the pivot wing 512, and the axle 168 is shown in elevation.

Figure 114 depicts a front elevation view of the axle rod.

Figure 115 depicts a rear elevation view of the axle rod. The rear of the pivot wing 512 is shown with the stop 18 against the shaft 12, so that the stop 182 keeps the pivot wing 512 in the oblique angle.

Axle Rod with Axle Receptacle - Figures 116-117.

An alternate embodiment of the axle rod is depicted in Figures 116-117. The axle rod 168 comprises the shaft 13 and the pivot wing 512 that is resting on bone 321. The shaft 13 is located within the bore 540 in the bone 321. A ligament 408 is suspended from the tissue retainer of the shaft 13.

In figure 117, the shaft 13 comprises two extended posts 441, 442 and a crossbeam 443 over which the ligament 408 is suspended. At the opposite end of the shaft from the ligament is a pivot wing 512. The extended member are secured to each other by a first transverse member, which is the pin of the pin hinge, a second transverse member, which is the tissue retainer, or crossbeam, 443 and optionally a third transverse member between the first two transverse members. This configuration can be used when the bone 321 is the femur and the ligament 408 is a graft of the Anterior Cruciate Ligament of the knee.

Split Suture Nut - Figures 118-131.

The split-nut of the invention can be used as a suture nut. In this embodiment, the split-nut is used for a non-threaded shaft, a suture, particularly in securing the suture S depicted in figure 120. The suture nut includes a band B and two split-nut sections c1 and c2. The band encircles and retains the sections C1 and C2. Figure 118 depicts the band B that is used to compress the section C1 and C2 of the split suture nut SSN. Figure 119 depicts the suture nut SSN with the band B surrounding the sections C1 and C2, and the suture s in the center. The sections C1 and C2 define a bore H around the suture S that serves to clamp the suture S when the sections C1 and C2 compressed together.

Figure 120 depicts the split suture nut SSN engaged with the lower longitudinal portion of the split suture n. The upper and lower longitudinal portions of the split nut include graded diameters, ramped surfaces. The upper ramped surface R1 of the split suture nut SSN engages the band B when the suture nut is compressed and the lower ramped surface R2 (shown in Figure 121) engages the band B when the sections of the suture nut are spaced apart.

In figure 121, the split suture nut SSN is depicted in partial section. The lower ramped surface R2 has an overall narrower diameter than the upper ramped surface R1, so that when the band B is around the Split Suture Nut SSN at the lower Ramp R2, the sections C1 and C2 are not compressed against the suture S. In the orientation of Figure 121, the split suture nut SSN is able to slide along the suture S forward and backward.

In figure 122, the band B in cross section and sections C1 and C2 in cross section, taken along lines Y-Y of figure 119. This figures shows that each section C1 and C2 is of unitary construction even though each section C1 and C2 has its own respective ramped surfaces. The ramped surfaces R1 and R2 are separated by the ledge L where the Band B reside when it is around the upper ramped surface R1.

Once the Suture Split-nut SSN is in place, the band is moved from the surface R1 to the surface R1 to cause the sections C1, C2, to clamp the suture S. In figure 123, the band B is shown approaching the ramped surface R1. This brings the sections C1 and C2 toward each other so that the hole H is narrower and almost clamping the suture S. This same position of the band is depicted in figure 124.

In figures 125 and 126, the band B has been moved even further along the lower ramped surface R2 upwardly toward the upper ramped surface R1. In figures 127 and 128, the bottom of the band is almost to the top of the ramped surface R2 and in proximity of the ledge L. In figures 129, 130 and 131, the band is fully engaged with the upper ramped surface R1 and held in place, generally irreversibly, by the ledge L. The band B holds the sections C1 and C2 together so that the friction surface H comes to bear on the suture S and hold the split suture nut SSN securely on the suture.

Although not shown, the sections C1 and C2 of the split nut can comprises even more ramped surfaces and ledges forming an overall stepped or ratcheting outer surface. Likewise, the band can comprise inner ramped surfaces that mate with the ramped surfaces of the split-nut.

The suture nut provides a very efficient method for applying fixation force to suture as its sections are fully cut longitudinally so they apply pressure their entire length. This device installs in small areas as it can be installed with a tube-within-a-tube instrument with one tube stabilizing the two sections, C1 and C2 while the other tube is used to pull the band, B, along the Ramp R2 until in place in Ramp R1. This double tube tool reaches the Split Suture Nut SSN along the suture, S, so that it can insert through a tiny incision that the Suture, S enters.

Crimping tools that are used in clamping a conventional fastener (not of the invention) around cable such as around bales of hay, require access to the Crimping tool be manipulated by one's hand from the side of the cable. Such crimping fasteners cannot install in small areas such as those allowed in surgery. The Suture Nut can install in small areas, where tools only of small diameter can be applied to manipulate the band, B, to move on the sections, C1 and C2, to clamp the suture, S.

The Transverse Flat Rod 227 - Figures 132 – 139

As depicted in figure 132, the transverse flat rod (or transverse impaction screw) 237 includes a tapered flat area 238 for receiving a ligament graft 227 (not shown). This area 238 is a non-threaded area. The rod 237 has threads 242 in a middle portion, for anchoring the rod in a bore of a bone, and a receptacle 241 for engaging a driving tool used to install and change the orientation of the rod.

Figure 133 depicts a side elevation view of the device including the flat portion 238. The flat portion 238 is skewed upwardly with respect to the linear axis of the rod. Figure 135 depicts a

partial sectional front elevation view of the rod, and figure 134 depicts a rear elevation view of the rod and its receptacle 241.

Figure 136 depicts the transverse flat rod 237 installed in a bone 251 having a bore 253 there through. The rod is installed such that its linear axis is about normal to the linear axis of the bore.

5 The rod is depicted with the non-threaded portion 237 in cross-section, and showing the flat section 238 with its short planar axis approximately parallel to the linear axis of the ligament 227 that is draped over it and to the bore 253. As depicted in figure 137, the rod 237 spans the width of the bore 253. The ligament 227 has been draped over the flat surface 138.

10 In figures 138 and 139, the rod 237 is depicted with the flat surface 238 approximately perpendicular to the linear axis of the ligament 227 and to the linear axis of the bore s53. When the rod 237 is in this position, the ligament 227 is pressed between the surface of the bore in the bone 251 and the edges 243 and 244 of the flat region. This compression of the ligament 227 into the walls of the bore 253 serves to create greater contact between the ligament 227 and the bone 251 and to promote healing.

15 ***Suturing the Ligament Graft - Figures 140 – 143***

Ligament is the fibrous tissue that holds two bones in register as they move. A tendon is the fibrous material that holds a muscle to a bone. To reconstruct a ligament a muscle is removed from the body, the fibers are taken from the muscle and this long strand of tendon is fashioned into a ligament.

20 Figures 140 – 143 depict a new method for constructing a ligament graft 27. According to this method, a ligament, such as from the Semi-Tendinosis Muscle, is harvested from the hamstring muscle group. The red muscle tissue is stripped to form a strip of tendon approximately 26 centimeters in length.

25 As depicted in figure 140, the ligament is made into a dual loop by passing the ends 27a and 27b of the ligament 27 twice through the eyes (tissue retainers) 15 and 15a. The ends of the ligament are then joined by suture so that the ends are on the side of the loop. The entire ligament loop is a dual strand that passes through the two securing means. The ends of the ligament are stitched together with suture 621 and the adjacent strands (loops 642 and 643) are then stitched to each with suture 622 other approximately along their entire length. This method provides an exceptionally

Variable	Mean	SD	Min	Max
Age	38.5	10.5	25	55
Gender	0.5	0.5	0	1
Marital status	0.5	0.5	0	1
Education	12.5	1.5	10	15
Income	3500	1500	1000	6000
Health status	0.5	0.5	0	1
Exercise frequency	0.5	0.5	0	1
Stress level	0.5	0.5	0	1
Sleep quality	0.5	0.5	0	1
Work satisfaction	0.5	0.5	0	1
Life satisfaction	0.5	0.5	0	1
Overall well-being	0.5	0.5	0	1